Master of Public Health

Master international de Santé Publique

Judicialization of on-list medicines in Brazilian municipalities: Examining inadequacies of the Brazilian National Health System's pharmaceutical assistance program

Louisa STÜWE
Year 2, 2011/2012
Paris
Professional advisor: Roberto Iunes, World Bank Institute
Academic advisor: Martine Bellanger, EHESP

Louisa Stüwe
Master of Public Health
EHESP

O medicamento é um insumo estratégico de suporte às ações de saúde, cuja falta pode significar interrupções constantes no tratamento, o que afeta a qualidade de vida dos usuários e a credibilidade dos serviços farmacêuticos e do sistema de saúde como um todo.[1]

A medicine is a material of strategic importance in the support of health care. Its lacking can entail constant interruptions in treatment, which affects the quality of life of users, the credibility of pharmaceutical services and the health system as a whole.

Louisa Stüwe
Master of Public Health
EHESP

Acknowledgements

Professional, academic and personal support from all team members of World Bank Institute, in particular:

Roberto Iunes, for his expertise, support in putting me in touch with his network of Brazilian contacts, attention to detail and patience in reviewing my purposes, and suggestions for orienting my study

Leonardo Cubillos, for bringing me on the team of the World Bank Institute's Regional Initiative on Priority-Setting, Equity and Constitutional Mandates between June 2011 and June 2012 and for his expertise on the subject and recommendation to use Brazil as a country for this study

María-Luisa Escobar, for her personal and professional support and availability

Janet Bonilla, for her personal support and interest

Academic support from many helpful Brazilians:

Denizar Vianna and Luciana Bahia, two very warm-hearted, generous and dynamic cariocas, for their strong personal and academic support

Sueli Dallari, Daniel Faleiros, Roselee Pozzan, Alethele Oliveros, Fernanda Terrazas, Paulo Picon and UFRGS team, in particular Amanda Quevedo, for their expertise, guidance, and availability

Staff of Municipal Health Secretariat of Rio de Janeiro (Secretaria Municipal de Saúde e Defesa Civil do Rio de Janeiro) for helping me to complete my questionnaire

Personal support in the daily process of my thesis writing:

Martine Bellanger, Vedran Aladrovic, Christopher Keel, my family and my friends

List of acronyms used

AF	Assistencia Farmaceutica – Pharmaceutical assistance
Anvisa	Agência Nacional de Vigilância Sanitária - National Agency for Sanitary Vigilance
Cadj	Central de Atendimento a Demandas Judiciais – Court service center
CF	Constituição Federal – Federal Constitution
Cirads	Comitê Interinstitucional de Resolução Administrativa de Demandas da Saúde
Conasems	Conselho Nacional de Secretários Municipais de Saúde - National Council of Municipal Health Secretariats
Conass	Conselho Nacional de Secretários Estaduais de Saúde - National Council of State Health Secretariats
DPE	Defensoria Pública do Estado – State Public Defendor
DPU	Defensoria Pública da União – Federal Public Defendor
Fiocruz – Fundação Oswaldo Cruz	Fundação Oswaldo Cruz
MS	Ministério da Saúde – Ministry of Health
PNM	Politica Nacional de Medicamentos - National Medicines Policy
PGE	Procuradoria-Geral do Estado
PGM	Procuradoria-Geral do Município
PU	Procuradoria da União
REMUME	Relação Municipal de Medicamentos Essenciais – Municipal Essential Medicines List
RENAME	Relação Nacional de Medicamentos Essenciais – National Essential Medicines List
SES	Secretaria de Estado de Saúde – State Health Secretariat
SMS	Secretaria Municipal de Saúde – Municipal Health Secretariat
STF	Supremo Tribunal Federal – Supreme Federal Tribunal
STJ	Supremo Tribunal de Justiça – Supreme Justice Tribunal
SUS	Sistema Único de Saúde – Unified Health System
TJ	Tribunal de Justiça – Justice Tribunal
UERJ	Universidade do Estado do Rio de Janeiro – State University of Rio de Janeiro
WHO	World Health Organization

I. Introduction

Brazil, like many Latin American countries, is experiencing demographic, epidemiological and nutritional transitions that have shifted patterns of health care needs towards a model based on chronic diseases[2]. Thus, medicines and treatments are producing higher costs not only per initial purchase, but also with regards to their long-term consumption.

One of the responses to better face this challenge has been a remarkable transformation of the Brazilian health system, introduced by the health reform of 1988. The new national health system that emerged from this process, known as SUS (Sistema Único de Saúde or Unified Health System), defined very ambitious principles and goals which were laid down in the National Constitution of 1988 and further detailed by two federal laws of 1990 (Law 8080 and Law 8142). The Constitution establishes the duty of the state to guarantee the right to health in its article 198f. Article 6, 196 and 200 of the Brazilian Constitution articulate the basic tenets and organization of the health care system: "*Health is a right of every citizen and a responsibility of the State, which should ensure, through social and economic policies (…) universal and equal access to the services and actions necessary for its promotion, protection and recuperation.*"[3]

Article 7 of Law 8080 reaffirms and clarifies these tenets in the definition of the principles of the SUS: a) "universal access to health services at all levels of care;" b) "integrality of care, understood as an articulated and continuous set of preventive and curative, individual and collective, actions and services required by each case at all levels of complexity of care of the system;" and c) "equality in health care without any kind of discrimination or privilege." These constitutional and legal provisions have been interpreted to mean that all SUS services must be provided free of charge to the entire population.[4] Law 8080 was amended in 2011 by Law 12401, with the aim to better define "integrality" of therapeutic assistance when it established the duty of the state to guarantee the right to health in its article 198ff.

Even though improvements in the organization of pharmaceutical assistance programs have been observed,[5] difficulties still remain with regards to guaranteeing effective access to needed medicines. In 2000, 41% of the Brazilian population lacked access to medicines.[6] According to the WHO definition, essential medicines are those that satisfy the priority health care needs of

the population.[7] In addition, household expenditure for medicines has been highly regressive as it represents the largest burden on health spending.[8]

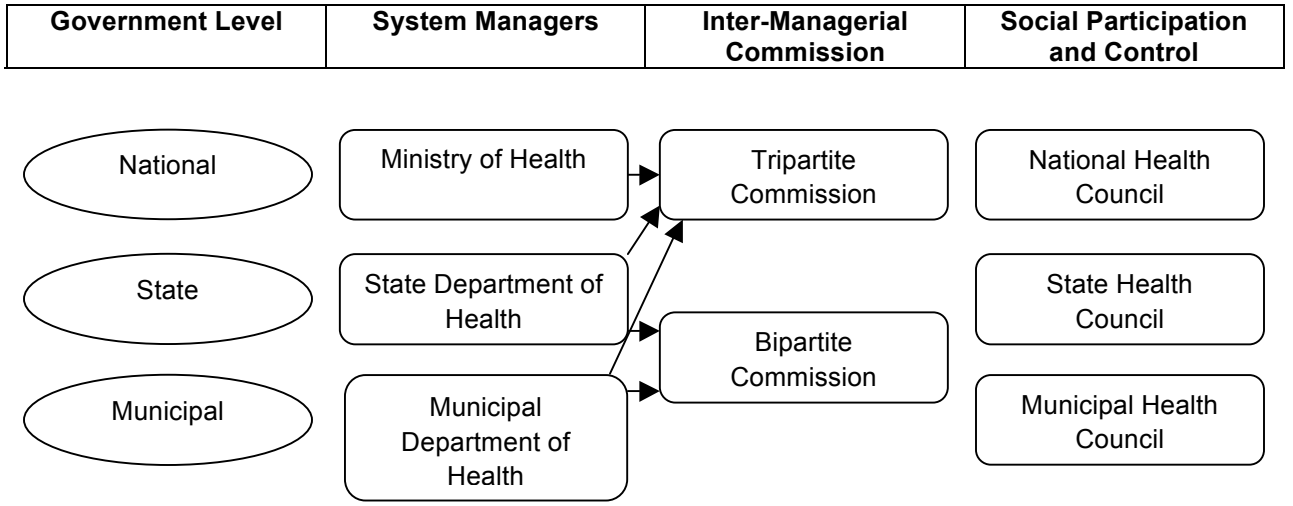
In this sense, a possible combination of this lack of access to medicines and citizens' increased awareness of their possibility to use the judicial system to pursue their constitutional rights[9] has led to an escalating number of lawsuits in Brazilian Courts since the end of the 1990s. The Brazilian constitution offers unconditional support for judicial involvement in determining the adequacy of the health care provided by the state.[10] This new role of the judicial system to guarantee individual rights has been identified as the "*judicialization of the right to health*".

As of 2011, there have been at least 241,000 health lawsuits throughout Brazil,[11] mostly for claiming access to medicines.[12] Most of these demands are individual demands, for specific health-care related goods and services, and are concentrated in the more developed states, such as Rio Grande do Sul – which represents the mayor burden of these lawsuits (113,953) –[13] São Paulo, Rio de Janeiro, Minas Gerais and Ceará (86,183 combined).[14]

Court orders for medicines are of immediate application and require considerable resources. As health budgets are limited and pre-determined by the law at least a year in advance, judicialization implies that health funds must be reallocated and health plans redrawn, especially taking into account that this phenomenon has been increasing at a rapid pace.

Since Brazil is a federal country, three different administrative levels need to be taken into account in order to correctly assess the costs of judicialization. The chart below shows that each of these different levels has a certain degree of independence, with regards to health system management, the allocation and organization of resources, and the representation via Health Councils.[15]

Figure 1: Institutional Structure of the SUS



At the *federal or national level*, lawsuits concerning the purchase of medicines ($US 47.6 million) and the judicial deposit ($US 6.1 million) amounted to around $US 53.8 million in 2010.[16] This marks a 46% increase compared to the previous year ($US 36.9 million), and a staggering 5269% or 53-fold increase in costs due to judicialization compared to 2005 ($US 1 million).[17]

According to Collucci, if judicialization is widespread at the federal level, it is significantly more so at the *state and municipal levels*.[18] This can be explained by the constitutional principle of decentralization[19], which requires that the execution of health services be gradually decentralized to states and municipalities. With regards to judicialization, for reasons of proximity, more claimants will choose to sue their municipality or state rather than the federal government, which implies that the number of lawsuits involving the federal government, although large and growing, only represents a fraction of the number involving states and municipalities.

Consequently, the state of São Paulo, in 2008 alone spent $US 153.6 million[20] in health lawsuits. This spending is 567% higher than that of 2006, when it amounted to $US 23.4 million. As for 2010, costs have been estimated to be around $US 268.8 million.[21] As for the state of Rio de Janeiro, according to government data presented by Teixeira,[22] in 2008 $US 128 million were spent on pharmaceutical assistance programs, which is much higher than the $US 35 million invested in basic sanitation to favor health promotion. At the General Prosecutor's Office, around 40 new claims for medicines are received per day on average. This means that in 2008, the State Secretariat spent R $ 11.1 million alone in compliance with judicial decisions.

Figueiredo et al.[23] divide these medicines into six categories, ranging from medicines mentioned on official lists to innovative medicines not yet incorporated by the Brazilian Health System (SUS).
The present study will focus on court orders for on-list medicines, which are supposed to be publicly available in the system. Court orders may reflect the failure of the management of public service or the failure of the administrative request system.

II. Current state of knowledge on the subject[24]

Despite the size of Brazil and of its economy, relatively little is known outside about the Brazilian health system and its current challenges.

With regard to judicialization in Brazil, and considering this as a rapidly increasing trend all over Latin America (e.g. Colombia), publications on this subject have only started to appear around 2005. However, English-language publications remain extremely scarce and do not yet reflect the important role that court orders for medicines have come to play as an alternative route to access medicines in the Brazilian Unified Health System (SUS).[25] Starting in the 1990s with requests for antiretroviral drugs, this type of lawsuit has been growing annually with claims for both on-list medicines – for reason of lack in the public sector as well as medicines that are not included on the lists and thus not yet incorporated by the SUS.[26] Even though the number of studies increased since 2005, such studies mostly relate to judicialization in a descriptive methodology (e.g. analysis of court orders) and are restricted to the situational diagnosis of either a state or a municipality. Thus, there is a clear lack of nation-wide studies to assess the impacts of judicialization.

We may point out as a reason that socio-economic and institutional characteristics can be fundamentally different from one state to another, and sometimes, between one municipality and another, making it therefore difficult to generalize results on a nation-wide basis. These differences in "prevalence and incidence" of judicialization all over Brazil are also mirrored in a very heterogeneous distribution of literature depending on the state, and a very low quantity of literature for less affected zones such as the North and Northeast States. Therefore, the number of people in different regions treading the judicial road differs starkly, with, as a general trend, litigiousness decreasing from south to north, from comparatively wealthier to poorer regions. That said, it is not merely relative affluence and its expected impact on such factors as education and rights consciousness, but also differences of local cultures, legal and political, and the resulting institutional framework that account for this difference.[27]

On the other hand, even though Rio Grande do Sul is the state with the largest number of claims, this does not positively correlate with the quality of the pharmaceutical assistance programs even though, according to a series of authors[2829], a higher demand should lead to greater improvements. As the phenomenon is increasing in importance in all different academic areas, the objective has now become that empiric studies be better systemized in order to better approach the national reality.

Furthermore, most of the studies have not specifically analyzed the reasons or performed a temporal analysis of the growth of the medicines claimed in court orders. There have been

important changes in the pattern of court orders, which have initially been focused on the claim for antiretroviral drugs. The pioneer cases were on access to HIV/AIDS drugs[30], with the first such action lead in 1996. Since then, cases for access to medicines have skyrocketed and have become a real concern for public authorities, especially since the claimed medicines now range from diapers to Viagra and include many high-cost items for rare diseases. A study by Messeder[31] that examined 389 (quantitatively weighed) individual actions against the state of Rio de Janeiro in the period from 1991 to 2001 showed that, until 1998, HIV/AIDS-related drugs amounted to more than 90 percent of actions, a figure that had dropped to just less than 15 percent by 2000. The reason was the slow start that the universal free HAART-drug dispersion program had in Rio de Janeiro.[32] What differs today is that there is an important demand of drugs that are not included on the official list of public funding, a gray zone where neither the federal nor the state or municipality are responsible for funding. Also, from 2000 onward, the picture of claims for medicines has diversified but still clusters around a number of medicines classified as exceptional by the SUS and linked to chronic conditions such as Crohn's disease.[33]

In some states, studies have identified a concentration of the prescriber and / or lawyer that give rise to litigation (Sao Paulo and Espirito Santo).
Other studies are focused on discussing the phenomenon from solely a legal viewpoint, by analyzing the content of court decisions as well as the judicial reasoning.
Yet there are still many gaps in research: few studies take into account ethnographic aspects of the claimants' profiles, as well as the motivation of patients to file a lawsuit, the real influence of the pharmaceutical industry in lawsuits (in patients and prescribers), the interaction between the General Prosecutor, pharmaceutical assistance managers and Secretariats of Health, the consequences of providing a patient with a medicine after a successful court order, or the long-term (health and socio-economic) outcomes for the patients and the motivations of patients who claim drugs but don't get to withdraw them.

There is also an important discussion in Brazil on whether or not judicialization widens inequities. According to Brinks[34], litigation is having a strong impact, with mixed consequences for democracy and distributive justice. In the case of Sao Paulo and Minas Gerais this seems to be confirmed, whereas in Rio de Janeiro and Rio Grande do Sul it is much less obvious. For example, even though it was shown that there were inequities in access to interferon, which plays a role in the first line of defense against viral infections, this was not linked to judicialization but to an inherent inequity of access to SUS.

That said, both routine access to medicines and on-demand access via administrative and judicial request systems are more easily given to the better-off parts of the population.

This master thesis hopes to contribute to filling the gaps in English-language papers on the issue of judicialization of on-list medicines in Brazil, including a case study of the municipality of Rio de Janeiro. For the latter, the administrative request system as an alternative to judicial claims has already been studied in depth.[35]

III. Study objective and Hypothesis

1. Study objective

The objective of this study is to assess challenges that municipalities, the municipality of Rio de Janeiro in particular, encounter in the implementation of pharmaceutical assistance programs, when facing an increasing demand for on-list medicines that should be regularly provided. As such, the study will retroactively assess effects before the national list was revised in March 2012.

2. Justification

Impact assessments of judicialization on pharmaceutical assistance programs at the municipality level are very important as they reflect the current lack of coordination of responsibilities between the three administrative levels. Furthermore, few or no English language studies have been published on this subject.

3. Hypothesis

An increasing trend of judicialization at the municipality level may further distort previously existing inadequacies in the pharmaceutical assistance programs of the SUS in delivering on-list medicines. Such inadequacies can be a general lack of funding or inefficiencies in the administrative system, in the procurement process for example.[36] The phenomenon of the lack of access to on-list medicines may also indicate several other possibilities, which will not be examined in this study but further discussed in the conclusion and discussion part.

4. Structure

First of all, it is useful to assess the impact of an increasing number of court orders at the municipal level, by quantifying and qualifying this trend (I) and, secondly, by evaluating to what extent this affects the regular cycle of pharmaceutical assistance activities, which is already characterized by a series of irregularities (II). In a third part, existing management responses to this problem will be identified and evaluated (III).

IV. Material and Methods

The methodological objective was to create a descriptive study including quantitative results from literature search and qualitative information from both literature results and interviews conducted on the field.

1. Quantification and qualification of judicialization trend

Articles dating after 2008 assessing the trend of judicialization at all three administrative levels were retrieved using SciELO databases[37], the Brazilian Virtual Health Library[38] and classical search engines.

A specific and recent dataset from the first semester of 2011, detailing quantitative and qualitative characteristics of judicialization was obtained from the Municipal Health Secretariat of Rio de Janeiro.

2. Impact assessment of judicialization on pharmaceutical assistance programs

Basic data and information about the health care system and pharmaceutical assistance programs were retrieved from the official websites of Brazilian health authorities at all three administrative levels.

A **literature review** was conducted in Brazilian and international publications, using SciELO databases, [39] the Brazilian Virtual Health Library,[40] JSTOR,[41] Science Direct,[42] PubMed[43] and the World Bank Library Network[44]. The time frame was 2000 to 2012 and key words that were used were (in English or Portuguese equivalent): judicialization, access to essential medicines, pharmaceutical policy, pharmaceutical assistance, medicines procurement, list of essential medicines, federal / state or municipal competence. Other articles were requested from a series of Brazilian interviewees (see annex).

Table 1: Results of Literature Review

63 scientific publications Time frame 2000 - 2012	**Key words:** - Judicialization, essential medicines, list of essential medicines, REMUNE, RENAME, lawsuits, court orders, pharmaceutical policy, pharmaceutical assistance, medicines procurement, federal or state or municipal competence
51 Portuguese-speaking publications	**Article types:** • 46 articles in international scientific journals between 2005 and 2012 • Seven of these 41 articles with core focus on Rio de Janeiro State or municipality • Five official government articles or bulletins from 2000 to 2011 **Databases:** • Brazilian Virtual Health Library and SciELO
12 English-speaking publications	**Article types:** • 6 specifically dedicated to the Brazilian judicialization case **Databases:** • JSTOR, Science Direct, World Bank Library Network, PubMed

In total, 58 publications were assembled. 48 of these were Portuguese speaking articles, of which 41 had appeared in Brazilian and international scientific journals between 2005 and 2012, five in the form of official government articles from 2000 to 2011 and two in the form of unpublished documents from 2012.

Experts identified for a first round of **interviews** in December 2011 represented all administrative levels and a variety of sectors, especially the academia and research institutions, the executive branch (Health ministry or administration) and the Judiciary (Attorney General, Federal and State judges). The goal of these interviews was to become more familiar with the topic and to narrow down the subject. Questions were open-ended and targeted at each of the interviewees' work areas, experience with judicialization in the specific work area, impact assessment and personal opinion about current trends.

Follow-up interactions with the academia were helpful in identifying Rio de Janeiro as a municipality for **in-depth research** and a second field visit was organized to Rio de Janeiro in April 2012. The state of Rio de Janeiro represents an interesting case where judicialization is growing but has not yet reached the same size as states as Rio Grande do Sul or Sao Paulo. The choice of a smaller entity the municipality of Rio de Janeiro was a strategic choice as data can be more easily retrieved and a unified contact set identified in the Municipal Health Secretary. The municipality is also a relevant example of a state level actor for which few impact assessments of judicialization have been conducted. Interviews were held with experts from the State University of Rio de Janeiro (UERJ) and the Municipal Health Secretariat of Rio de Janeiro, as well as via e-mail exchanges and telephone correspondence with other experts, using a questionnaire with open-end questions as a basis (see annex). However, the questionnaire could not be submitted in written format as to use this information, because since January 2012 a national approval by an official Ethics Commission is mandatory. For a non-Brazilian researcher, very strict rules apply to obtain this approval. Not only does the non-Brazilian researcher need to be officially affiliated with a Brazilian host research institution, but also he or she must wait around 6 months for approval.

As **next steps** beyond submission of this study, results will be extended after approval of the Ethics Commission has been granted in the third trimester of 2012. The questionnaire and results evaluation could also be used for other municipalities in order to be conducted in a nation-wide comparison.

3. Management responses

This analysis relies on the same sources as the previous section, but most importantly on the above literature review, an official document obtained from the Municipal Health Secretariat of Rio de Janeiro detailing management responses as well as interviews and other correspondences with Brazilian experts (see interview schedule in annex).

V. Results and interpretation

After assessing quantifying and qualifying judicialization at the municipal level (1), the impact of this trend will be assessed at the municipal level (2). This assessment will be completed by an assessment of existing management responses and their effectiveness (3).

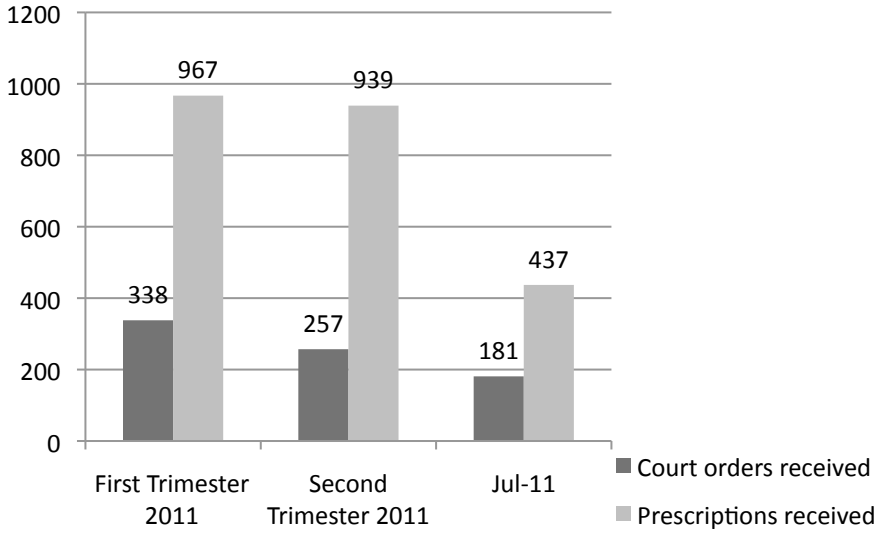
1. Judicialization at the municipality level

The first sub-section analyzes the types of medicines predominantly claimed in a typical municipal setting, using Rio de Janeiro as a case study. The second sub-section studies the impacts of judicialization of on-list medicines in the fulfillment of PA programs and third the management responses to judicialization of on-list medicines.

A. Quantitative assessment of judicialization: case study of municipality of Rio de Janeiro

As it has been shown that lawsuits often differ with regards to thei claimed object between the different administrative levels, and that no unified statistics are yet brought to light providing a comprehensive picture of the Nation, it makes sense to pick out a municipality and a limited time frame for a case study and to provide information about the lawsuits at the micro-level.

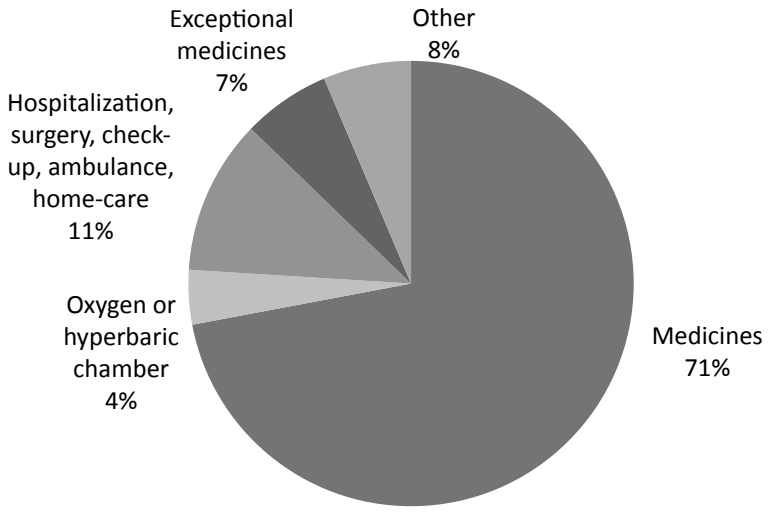
Figure 2: Numbers of court orders and prescriptions received between January and July 2011 in the Municipality of Rio de Janeiro



The State of Rio de Janeiro consists of 92 municipalities, with Rio de Janeiro City as its capital. Its population as measured in 2010 by the population census bureau[45] counted 6,320,446 inhabitants.

Information on the judicialization of medicines in the municipality of Rio de Janeiro was obtained from the Municipal Health Secretariat of Rio de Janeiro[46]. In the first semester of 2011, a total of US$ 3.7 million was spent on medicines and services obtained through the Courts. US$ 2.1 million (57%) of this sum was for the purchase of medicines and US$ 825,652 (23%) for the purchase of services.

Figure 3: Percentage of types of claims for court orders and prescriptions received between January and July 2011 in the Municipality of Rio de Janeiro



With regards to the management of court orders, 338 were received in the first trimester of 2011, 257 in the second semester and 181 in the month of July alone.

As for prescriptions, 967 were received in the first trimester of 2011, 939 in the second trimester and 437 in the month of July. As the graph shows below, one can detect a 32% decrease of the second trimester compared to the first with regard to received court orders. With regards to prescriptions received, this percentage seems more or less stable.

The graph above shows the demand for different types of medicines and supplies. Between January and July 2011, 71.1% (552 out of 776) of court orders were based on medicines and supplies, partly on a permanent basis, 3.9% on oxygen or hyperbaric chamber, 11.1% on hospitalization, surgery, check-up, ambulance, home-care, 6,3% on exceptional medicines and 7.6% for other purposes. A more detailed overview of this case set is in table 4 in the annex.

In the State of Rio de Janeiro, it was observed that 32% of patients who had formulated court orders for exceptional component medicines between July 2007 and June 2008 did not present themselves in the state health Secretariat to receive their medicines.[47]

The previous dataset provides an interesting snapshot of the types of lawsuits in a given municipality and time frame. However, in order to assess both the types of authors behind the

lawsuits, and a more in-depth assessment of the types of claimed medicines, especially, if they belong or not to the official list, it makes sense to review literature to provide statements.

B. Characterization of lawsuits by on-list nature of object of claim

The dataset of the first subsection provides an interesting snapshot of the types of lawsuits but does not provide sufficient information about the percentage difference of medicines part of official lists or not. Thus, we will seek information on the percentage of cases for on-list medicines at the State level (as more information is available), in order to be – in a second step – able to assess the impact of judicialization of pharmaceutical assistance activities for on-list medicines.

Table 2: Distribution of claimed medicines, according to presence in financing components of the Pharmaceutical Assistance Program. State of Rio de Janeiro, July 2007 to June 2008.[48]

Component				N	%
Exceptional	Basic	Strategic	None		
			x	229	**66.6**
x				69	20.1
	x			37	10.8
		x		4	1.2
	x	x		2	0.6
x	x	x		2	0.6
x		x		1	0.3
Total				**344**	**100**

Pereira et al, (2007)[49], Vieira and Zucchi (2007)[50], Messeder et al (2005)[51], Romero (2008)[52] and Pepe et al (2008)[53] are more or less on the same line of study when they state that the majority of claimed medicines are not part of any of the official lists. With regards to the State of Rio de Janeiro, Pepe et al.[54] examined 185 lawsuits demanding medicines that had already followed an appeal, brought in front of the Courts of State of Rio de Janeiro in the year of 2006 and which futhermore all claimed on-list medicines. Pepe et al. found that 316 different medicines were object of claims of which 48.1% were part of the National List of Essential Medicines, the Exceptional Dispensation Medicines List and other official lists of medicines. 51.9% were not present in any of the official lists of medicines and 80.6% of court orders included at least one medicine not present in the official list.[55] These results suggest that medicines are usually claimed in "packets." In more than half of the cases, medicines are not part of the lists. For the other half, on-list medicines are the object for claim, and they are often claimed in combination with an off-list medicine.

From mid-2007 to mid-2008, a study by Figueiredo et al.[56] studied individual lawsuits brought in the courts of the State of Rio de Janeiro during a period from July 2007 to June 2008. For 281 plaintiffs, 804 demands were filed, corresponding to 356 medicines and to 269 pharmaceutical substances. Of these, only 33.4% belonged to the 2006 National EML (RENAME) (see table above).
With this information available about the State of Rio de Janeiro, it is interesting to draw a comparison with existing data from other municipalities or States. A majority of studies have shown that medicines which are not part of the public lists are more common, for example in Espirito Santo, Minas Gerais and Rio de Janeiro.

With regards to the State of Minas Gerais, Machado et al.[57] conducted a study analyzing 873 lawsuits for medicines at the State level between July 2005 and July 2006. 43.9% of medicines were part of official lists, of which 19.6% were included in the National list of Essential Medicines (REMANE) and 24.3% part of the Exceptional Component (*infra*).

As to the municipality of Sao Paulo, Vieira and Zucchi[58] found in a study of 170 cases brought against the Municipal Secretary of State in the year of 2005 that almost two thirds (62%) of the medicines claimed through litigation were part of official lists. This contradicts a study conducted by Chieffi and Barata[59] using 2006 data for the same geographic entity, which found that 77% of the claimed medicines were not part of the government's pharmaceutical assistance programs of the SUS, out of a total of 954 issued medicines. Of the quarter of claimed medicines found on official lists, 12% were part of the Exceptional Component. Differences in the obtained results might simply point out a different year of analysis and major improvements in access to essential medicines during 2005, causing their relative percentage to decrease in 2006. Differences may result from the use of distinct methodologies as Chieffi and Barata used data from the Electronic Registry System of the São Paulo State Health Secretariat, whereas Vieira and Zucchi used standardized forms.
Even though there are differences in the exact amount of judicialized medicines on the official lists, the question of the adequacy of the current official lists of medicines within the public pharmaceutical assistance program of the SUS is still primordial. More specifically, it is important to examine the inclusion criteria and mechanisms of handling effective distribution of medicines to the population as well as the possible influence of the pharmaceutical industry to push for incorporation or a lack of use of clinical protocols, or their lack of updating, by health professionals. The most obvious concern of this study is to examine how judicialization affects

the way on-list list drugs are acquired and dispensed. As we will later see, the municipality level is mainly in charge of assuring the primary care level to the patients and is therefore chosen as the focus level for this study.

2. Impact of judicialization on pharmaceutical assistance activities at the municipality level

The high intensity of litigation may interfere with the fulfillment of all cycles of pharmaceutical assistance activities. Before assessing such impacts, it is important to present the key pillars of pharmaceutical assistance programs.

A. Organization of pharmaceutical assistance programs at the federal, state and municipal level and current challenges

The Brazilian pharmaceutical assistance program has the objective to guarantee the population's access to essential medicines, which are those that satisfy health needs and are available to all in adequate quantities and appropriate dosages, proving their adequate and rational use.[60]

With regards to pharmaceutical assistance programs, these consist of a set of systemic, complementary and multidisciplinary activities articulated as a cycle, including selection, planning, acquisition, storage, distribution and use (including prescription, dispensation and use). Figure 4 in the annex details this cycle. Pharmaceutical assistance programs have become an important element of the SUS with the establishment in 1998 of a revised National Medicines Policy, the First National Conference on Medicines and Pharmaceutical Assistance in 2003 and the National Pharmaceutical Assistance Policy in 2004.[61]

All three administrative levels of government – federal, state and municipal are responsible for funding PA programs, each of them with different responsibilities and duties with regards to medicines dispensation. These competencies are not explicitly stated in the Constitution or law, but outlined in numerous federal, state and municipal administrative decrees. The main one is Ordinance No. 3.916/98[62], which states in its article 1 that the Ministry of Health establishes the National Medicines Policy (NMP).

Two parts of the pharmaceutical assistance cycle are of particular relevance for this study, namely exploring the mechanisms of selection of medicines and the distribution of responsibilities for planning.

i. Selection

The **National List of Medicines (RENAME / Relação Nacional de Medicamento)** is part of the NMP, which is updated every two years.[63] Selection of medicines should be based on the best available evidence and take into consideration levels of morbidity, prevalence, drug efficacy, effectiveness, safety and quality, pharmaceutical forms meeting the needs, dosage convenience, cost and market availability. Especially with the publication of the new RENAME through Directive 533 of March 28, 2012, it is becoming clear that the inclusion of a medicine is not considered to be a method of financial austerity but rather an exercise of clinical intelligence and management. Thus, the high cost nature of a medicine does not exclude it from the list if this medicine represents the best choice for an epidemiologically relevant condition.[64]

Previous lists included only primary care essential medicines to respond to the most prevalent diseases of the Brazilian population. Medicines for rare and complex diseases, vaccines and medical supplies were mostly excluded, The updated RENAME has been expanded from 550 to 810 items and now includes all outpatient prescription medicines, including medical supplies and vaccines. According to Carlos Gadanha, Secretary for Science, Technology and Strategic Inputs, enlarging the list is the next step of the national strategy that links access to medicines, rational incorporation of new medicines and further signals the increase of domestic production. However, a set of items remains excluded in the 2012 RENAME, notably cancer and ophthalmic medicines as well as those used in emergencies.

Taking into account that Brazil is the largest country in Latin America with approximately 8.5 million square kilometers (3.3 million square miles), and the world's fifth most populous country with almost 191.5 million inhabitants in 2009, one can consider that public health necessities are very different among the different administrative levels. Consequently, municipalities define their own **Municipal List of Essential Medicines** (REMUME/ Relação Municipal de Medicamentos Essenciais), based on RENAME, and implement the PA programs. On this basis, municipalities ensure the **supply of medicines intended for primary care** and of other on-list medicines that are defined in the Municipal Health Plan.[65]

The *municipality of Rio de Janeiro* has its own 2008 Municipal Register of Essential Medicines (REMUME), which was recently revised, by means of Resolution SMS nº 1364 of July 4, 2008.[66] It consists of all medicines used in the Municipal Health Secretariat, either directly acquired or through direct transfers of strategic programs of the Ministry of Health and the State Secretariat

of Health.[67] The list includes more items than the RENAME, with more antihypertensive medicines for example. According to interviews conducted in Rio de Janeiro regarding the types of medicines, they have historically been chosen based on the demands of different vertical health programs (diabetes, hypertension, women's health, among others). At one occasion, an effort was made to standardize this selection, quantity and procurement and Rio de Janeiro's REMUME was published, and a formal review followed.[68]

ii. Responsibilities

Since 2006 and the publication of the Directive No. 698, the pharmaceutical assistance program is considered a specific financing block of the SUS. Generally speaking and as outlined by various health care professionals[69], and leaning on Law 8080 Law, "the Union takes care of high medical complexity (cancer, AIDS, important national endemic diseases which require large investment in research), the State takes care of medium average complexity and the municipalities of basic pharmaceutical assistance."
The Directive GM/MS nº 2.982 of November 26, 2009 regulates the financing block for the pharmaceutical assistance in three components: **basic, strategic and specialized**.[70]

The **Specialized Component** is used for treatment of specific pathologies, affecting a limited number of patients, and at high cost, either for a high unit value, or their use for longer periods. Among the users of these medicines are transplant recipients, patients with chronic renal failure, multiple sclerosis, chronic viral hepatitis B and C, epilepsy, chronic intractable schizophrenia and genetic diseases such as cystic fibrosis and Gaucher disease.[71] Medicines of this component are divided into three groups and according to each group the Union or the States and the Federal District are in charge of acquisition and distribution. The first group is for medicines for complex diseases treated in an ambulatory care, for which the State is responsible either via centralized procurement or resource transfer. The second group is targeted at the guarantee of treatment integrity for which the States and Federal District are entirely responsible. The third group is for maintaining a financial equilibrium between the different administrative levels, for which the municipalities and the Federal District are responsible, according to Directive GM / MS no. 2.982/2009.[72]

The **Strategic Component** is used to pay for public health programs related to the control of endemic diseases such as tuberculosis, leprosy, malaria, leishmaniosis, chagas, STDs and anti-

retroviral drugs, blood and hemoderivatives, and Immunobiological products. The Union is in charge for their acquisition and direct distribution to the State or Municipal Health Secretariats.[73]

The **Basic Component** is based on RENAME and intended for the acquisition and distribution of medicines and medical supplies through transfers of funds to states and / or municipalities or via the centralized medicines procurement program defined by the Ministry of Health, CONASS (National Council of State Health Secretariats) and CONASEMS (National Council of Municipal Health Secretariats). [74]

For the purchase of the Basic Component, the Ministry of Health transfers a fixed per capita rate of R $ 5.1 per year to the Municipal or State Health. This is completed by a state and municipality financial contribution of R $ 1.86 per capita inhabitant per year for each.[75] For specific public health programs, there is also a variable per capita part to purchase medicines for Hypertension and Diabetes, Asthma and Rhinitis, Mental Health, Women's Health, Food and Nutrition and Anti-Tobacco Programs. The implementation is in most of the cases a decentralized process, the exception being for example human insulin which is purchased by the Ministry of Health and distributed to managers, and the responsibility lies with the municipalities, the Federal District and the States. For its proximity to the population and capillarity, the municipal level is the most relevant level for the implementation of the Basic Component. For its proximity, it is also often seen as the responsible level for responding to any kind of judicial claim - be it for the Exceptional, Strategic or Basic Component (*infra*).[76]

iii. Purchasing

Procurement is an important part of efficient medicines management and supply and is an important procedure for all levels of health care institutions.[77] A reliable drug procurement program must first consider what (selection), when and how much (programming) is purchased and by means of what procurement process. Monitoring and evaluation of these processes are essential to enhance management and intervene in case of problems.

Purchases can be made through competitive bidding ("*licitação*"), without bidding or enforceability of bidding. Bidding is the administrative procedure for contracting services or acquisition of products through Public Administration entities, determined by art. 37 – XXI of the Federal Constitution of 1988 and regulated by the law nº 8666/93 and the law nº 10520/02, imposing a duty to government bidding. The bid is intended to ensure compliance with the constitutional principle of equality and selection of the most advantageous proposal to the Public

Administration. Guiding principles are legality, impersonality, morality, equality, publicity, administrative probity, a link to the calling instrument and an objective judgment. It should be processed with the official laboratories or through the price registration system.

In the State of Rio de Janeiro, by means of Resolution SES No. 2.471 of July 20, 2004, the State Health Secretariat created a Technical-Operational Committee, with the functions of acquiring, storing and distributing medicines that are of State competence. In addition, a Board of Managers of the State Medicines and Pharmaceutical Assistance Policy (*Colegiado Gestor da Politica Estadual de Medicamentos e Assistência Farmacêutica*) was created by SES Resolution No. 2600 of December 2, 2004, whose function is to assist the State Health Secretariat in the management of pharmaceutical assistance.

According to information obtained from the Municipal Health Secretariat and interviews conducted in Rio de Janeiro[78], the Pharmaceutical assistance program of the Municipal Health Secretariat bases the purchasing process on a historic series to formulate the new procurement competitive bidding processes. Recently, with a considerable expansion of coverage of the Family Health Program as part of primary care, these amounts have been very fluctuating but could not accessible for public information yet.

B. Impacts of judicialization on the fulfillment of pharmaceutical assistance programs at the municipal level

The high intensity of litigation may interfere with the fulfillment of all cycles of PA activities. After assessing the perceived impact of judicialization on municipalities (i), it seems relevant to examine to what extent impacts on the fulfillment of pharmaceutical assistance programs at the municipal level could be related to (ii) distortions of the previously determined purchasing responsibilities of components by the administrative entities, (iii) forced provision of an on-list medicine via injunction, and (iv) an improved organization on the long-run.

i. Perceived impacts by municipalities

Much discussion is currently on the potential of court orders to disorganize the SUS. Court orders may affect both budget as well as administrative issues, when they determine the delivery of medicines via injunction and if these are not the responsibility of the municipality.[79] To find out how the lawsuits for treatments and medicines have affected municipal health management, a survey conducted in 2009 by Octavio Ferraz, Daniel Wang and Blenda Pereira, with institutional support of CONASEMS (National Council for Municipal Health Secretaries), a

survey was sent to all municipal health secretaries to enquire about the impact that judicialization has on their budget. In total, 1,276 municipalities responded, representing 23% of the total 5566 municipalities. 34% of these municipalities responded that there the growing number of lawsuits claiming health services and medicines perceiving this as an important problem, 23% responded that there is an important growth of judicial demands but that it does not yet represent a major problem and 46% said that they had until then not identified this trend as a problem.

These results show that a third of this relevant sample of municipalities acknowledges that an increasing importance of lawsuits for medicines is becoming a problem, especially for the budget consequences at the municipal level.[80] The fact that only a bit more than half of the sample has clear awareness of an increasing trend of judicialization could point at the fact that judicialization is indeed distributed unequally among the different Brazilian regions, or that even though the trend has started in some municipalities, efficient responses have neither been designed nor implemented.

ii. Distortions of purchasing responsibilities between administrative levels

According to data obtained by the Municipal Health Secretary of Rio de Janeiro[81], it has been found that 90% of the items requested through lawsuits were part of the so-called gray zone, where there is no definition of which entity has the obligation to respond, ranging from medicines, home care, home oxygen therapy to special insulins, as seen in the first chapter.
Another interesting factor is that Pepe et al.[82] found that defendants included, in 36.8% of a sample lawsuits (*supra*), more than one government entity and in most of the cases both state and municipality.

Clearly, judicialization of health in Brazil has emerged as a process that not only generates unexpected costs at different administrative levels, but also regressive costs, that weigh mostly on municipalities which are the entities with least financial resources.[83]

One of the major problems identified in interviews throughout Brazil at the State and Municipal Health Secretariat level was the issue of “joint liability”. The Court of Rio de Janeiro, as well as several other Justice Tribunals (Tribunais de Justiça) and Superior Courts (STF and STJ) have already made clear that the matter of "health" is a joint liability among all administrative levels of the Federation. The investment of the principle of joint liability has been laid down in the

Brazilian Civil Code, which states in its Article 275: *in the presence of multiple debtors, the creditor may require compliance with the obligation on the part of all, of some or only one, since each debtor is obliged for the integrity of the debt*. It is on the basis of this legal norm that judges understand that the citizen is the creditor of the State's obligation to guarantee the right to health by means of the SUS. As the SUS is a system composed of federal, state and municipality levels, these entities represent the multiple debtors of this requirement and are therefore jointly liable. However, the same Civil Code specifies in article 265 that solidarity is not presumed; results of the law or the will of the parties.[84]

Joint liability has also been mentioned as a concern by the superintendent pharmacist of the municipality of Rio de Janeiro, noting that the solidarity clause is not valid with an increasing trend of judicialization that predominantly weighs on municipalities' "budgets".
Indeed, by means of injunctions pronounced by the judiciary, municipalities are often brought to purchase highly expensive drugs, for example of the Strategic or Exceptional Component which are usually not part of their area of responsibility.[85]

Further, Teixara has found in a series of interviews that there is a relationship between a certain "disengagement" of the Union with regard to the so-called gray areas of medicine.[86]
Recently, in the State and municipality of Rio de Janeiro, an agreement has been found so that judicialized medicines that are regularly part of REMUNE should also be paid for by the municipality in response to the claim, and that those which are part of the State responsibility be also paid for the State. The problem obviously lies with those medicines which are part of no list and where there is missing responsibility.

iii. Inclusion of non-list items and related risks

1. Inclusion of non-list items

Once a certain litigation density has been reached, public authorities tend to seek cover by including the medicine in the SUS list or the therapeutic consensus. In the Federal District, Romero[87] identified that court orders for multiple sclerosis treatments had dropped, after the Clinical Protocol and Therapeutic Guidelines (PCDT) for this pathological condition had been approved in 2002. In the same way, in Rio de Janeiro, Messeder et al.[88] also observed a reduction of court orders for antiretroviral drugs for HIV / AIDS after they had been incorporated in REMANE in 1996.[89] This pioneering HAART case showed that litigation can work as a

signaling mechanism for demand in new medicines, and, hence, for the expansion of an existing public policy.

Another example from Rio de Janeiro concerns four leukemia cases brought by a private attorney on behalf of three paying (i.e. middle class) and one pro bone indigent patient in relation to unlisted leukemia medication. All plaintiffs won their cases, and medicines were initially distributed, though, in one case, distribution was subsequently discontinued. Renewed legal action then resulted in a prison mandate for the municipal health secretary in the case of continued noncompliance. Eventually, the medicine was included in the SUS list and distribution regularized.[90]

2. Risk of new inclusions

There are two main risks related to the inclusion of medicines previously not on the official list: security and equity concerns.

First, court orders for the supply of non-list medicines can interfere in a way that disregards the classical pharmaceutical assistance cycle process, and adjusts it an accelerated cycle. In an emergency or segmented purchase, there is not sufficient planning and programming in the procurement process, and the lengthy call-for-bids procedure in the procurement process often passed by. This can then lead to budget distortions as medicines are not purchased at regular competitive prices.

Second, the example of a 2004 court order affirming the allocation of medicines in the Justice Tribunal of Rio Janeiro[91] shows that Brazilian jurisprudence has been supporting an individualistic approach to social problems. As such, inclusion can be seen as a biased approach as court orders are not an equal representation of the population, but only of those who can access the courts.

As stated by Ferraz (2009) [92], "access to the courts in Brazil is significantly easier for those with resources and social attributes that are more predominant in higher socioeconomic groups." According to Siri Gloppen[93], these resources and social attributes include "rights awareness; organizational strength and ability to mobilize; and access to legal assistance, technical expertise, and financial resources." Several other empirical studies on the phenomenon of health litigation confirm, predictably, that a significant portion of successful litigants do not belong to the most disadvantaged layers of society, but rather the opposite (e.g. Fernanda Terrazas[94]).

This could also go against the main foundations of the SUS: universality, equity and integrity of health care services.[95]

iv. Impacts of court order injunctions

Even though, principally the negative effects of judicialization have been outlined at the municipality level, one can also outline a series of positive effects that might result from this trend at the organization level of pharmaceutical assistance programs.

In this perspective, one can first of all operate a distinction between the definition of administration of a medicine and implementation of the medicines program. Whereas the former relates to the administrative decision to include a new item in the list of medicines to be distributed by public pharmacies,[96] implementation relates to the de facto carrying out of that policy so that the medicine is actually available in the public pharmacy in sufficient quantity. In part the reasons for non- or insufficient implementation are legitimately linked to a lack of organization and structuring of pharmaceutical services, including time-consuming public procurement, price negotiation, and registration issues. For this, efficient management requires qualified personnel and a basic adequate structure and may contribute considerably in improving access, solving routine problems and streamlining purchasing procurement and dispensation procedures with positive impact on healthcare coverage.[97]

Yet, in other circumstances, various forms of maladministration including inertia, incompetence, haggling between authorities, or political impasse are the reason for the failure to distribute medications. In this later case, litigation serves as a corrective action for negligence on the part of the public authorities.[98]

Although this can be said to have a positive effect on policy implementation, it may also have the flip side of making public authorities more or less deliberately wait for judicial mandates until they implement the policy in an incremental way. Given the overall scarcity of resources and lack of consensus on how to best spend them among policy makers, the latter attitude may be quite frequent.[99]

Having assessed not only typical patterns of judicialization at the municipality level and impacts on the implementation of pharmaceutical assistance programs, it seems relevant to assess the management responses that have been set up at the State and municipality level, with the perspective of alleging the burden of the municipalities in this trend which has been mainly affecting them.

3. Management responses to judicialization of on-list medicines

The judicialization of health has entered the agenda as a problem for which one had to begin to think about the formulation of alternatives[100] that would minimize both the high affluence of demands in the courts, as well as the fulfillment of decisions that often meant significant budget portions and important sanctions in case this fulfillment was not complied with. Over the past years, efforts were made from both sides towards better collaboration and in various States of the Federation, there have been suggestions for agreements, committees, and systems involving the Judiciary, prosecutors and the Executive. [101] It seems coherent to analyze in a first part those efforts that have been made towards the Judiciary (A), secondly to weigh the pros and cons of a completely new mechanism called Administrative Request System (B) and other alternatives (C).

A. Existing management responses by the Judiciary and Executive branches

i. Improving responsiveness and structure of judicial request system

The conflict between public administration and the Judiciary seemed to be permanent with no perspective of "ceasefire". As stated in one of the interviews conducted in Rio de Janeiro, it occurs that a judge in the situation of making a decision mistakenly assumes that what is prescribed by the doctor is adequate and correct.

Some municipal and state pharmaceutical assistance programs have considered court orders in their pharmaceutical assistance cycle to better meet the demand, by creating Technical Councils to assist the Prosecutor in the demands related to the right to health. For example, the Directory of pharmaceutical assistance of the State Health Secretariat of the Federal District schedules the acquisition of medicines for court orders in different ways, depending on whether the drug is included in the REMUNE and/or whether there is stock availability.[102]

In Rio de Janeiro, as of 2004, in response to the high financial burden on municipalities as a result of judicialization, a so-called secondary track planning and purchasing system was organized, in the response to court orders. A Technical Operations Committee was created, with the mandate to acquire, store and distribute medicines, which are in the realm of state competence. Further, by means of SES Resolution no. 2,600, of December 2, 2004, a State Policy Managers Board for Medicines and Pharmaceutical Assistance was created, with the function to assist the Secretary of State in the management of pharmaceutical assistance activities and thus allege the burden on the municipalities.[103] As of 2007, by means of the joint resolution No. 36 of July 17, 2007 between the State Secretariat for Health of RJ and the

Municipal Secretariat for Health for RJ which provides for a joint structure to centralize the handling of these lawsuits. There has also been the Municipal Health Plan for Rio de Janeiro - 2010 to 2013, containing a chapter guiding on how to "*Better structure and qualify the responsiveness to lawsuits*". The following objectives have been set: 1) to systematize information specific to the lawsuits, 2) to build a database for analyzing the effectiveness of the system, 3) to set criteria to rationalize and optimize the handling of lawsuits and 4) to establish a service for handling lawsuits in the program area.
Process 09/003254/2011 foresees the construction of a new system of warrants, for an estimated cost of R $ 360.000,00 for this "Iplan", and a timeline of 18 months for implementation, after the second half of 2011.

ii. Administrative Request System

1. Mechanism

In some States, such as Paraná, Espírito Santo and Rio de Janeiro, the administrative request system has been conceived as an alternative for court orders to claim medicines, including those that are not present on the official public lists. This system has been implemented either within the health sector, as is the case of Paraná and Espírito Santo, or by agreement between the Health Secretariat and the Public Defender, as in the case of Rio de Janeiro. The administrative request system allows the patient to receive the medicine more quickly than by means of the lawsuit. It doesn't cause either interferences in the management of pharmaceutical assistance programs in the same way as lawsuits do and the financial burden for the municipalities is reduced because their responsibility is clarified.

In the State of Rio de Janeiro, a multi-stakeholder collaboration agreement between the State Solicitor's Office and Municipal Solicitor's Office of Rio de Janeiro, as well as the Municipal and State Health Secretaries, has been established with the Public Defender of the State of Rio de Janeiro, with the objective to create alternatives to the growing process of judicialization that is weighing on the public budgets. In 2008, the administrative request system was initiated to expedite the supply of medicines to the population that seeks the Public Defender for such demands.[104] A detailed scheme of this system can be found under Figure 5 in the annex.

As a result of the administrative request system, the number of court orders for medicines claiming the right to health has considerably decreased. [105] The Public Defender requires that prescriptions indicate the active principle of the desired medicine, and establishes a period of 45

days for the referred Health Secretaries to deliver the medicine to the claiming patient. In an emergency, the Public Defender's Office can also propose an accelerated lawsuit in the name of the patient directed at the Health Secretariat that defines the responsible entity for that type of medicine.[106] These measures are intended to expedite the process of access to medicines by the population, and will also reduce the costs that can be avoided to public budgets, as responsibilities are better disentangled. Negative budget impacts at the municipal level due to the joint liability clause are therefore tempered.

Interviews conducted in Rio de Janeiro have shown that this system is also closer to the patient. In the case of medicines of the Basic Component and thus of municipal responsibility, these can be withdrawn at a clinic close the patient's residence, while if the medicine is obtained via court order, this process is more complicated, obliging the patient to withdraw the medicine not in a specific Lawsuit Management Center (Gerência de Atendimento a Mandado).

With regard to medicines of the Exceptional Component which are thus of State competence these can be also be obtained via the administrative request system. Patients registered in the program retrieve such medicines in the so-called "Riofarmes"[107], introduced in 2010, a public entity that dispenses medicines of the Exceptional Component, such as for chronic renal failure, viral hepatitis B and C, anemia, osteoporosis, growth failure, Alzheimer's disease, Parkinson's disease, Gaucher disease, among others. Located in Cidade Nova, in the Center of Rio de Janeiro it combines patient registration and medicines dispensation in one entity. It had around 56 million patients in 2011 registered in the State of Rio de Janeiro marking a 20% increase compared to 2010, and a daily coverage of 1300 patients (with capacity of up to 1500 per day).

The feedback of patients towards this mechanism have been very favorable for the high management efficiency and a contrast to a previous lack of such centralized place existed and in the case of lack of access to medicine, presenting a court order was the only viable solution, which would furthermore have to renewed after the period consented by the Judge had expired.
Therefore, the mechanism of the administrative system request allow to consider a breakthrough in the attempt to reverse the trend of judicialization of pharmaceutical assistance programs on a State and Municipal basis, most importantly with the effect of alleging municipalities' budget as responsibilities are affirmed in practice[108] and disengaging the Judiciary while returning this responsibility to the Executive. Graph 3 in the annex provides a very clear overview of the functioning of the administrative request system.

2. Challenges

According to the interviews conducted in Rio de Janeiro, however, even though this system proves efficient to oblige the adequate administrative level to distribute medicines for which responsibility has been clarified, there is still missing response capacity with regard to medicines from the gray zone.

Medicines of the gray zone are those whose use has not yet been standardized by the protocols of the public health system. The actors show this as the biggest obstacle to better performance of the Administrative Request System as an effective alternative to the process of judicialization. It has thus been pointed out that a significant decrease in court orders for medicines after implementation of the system has not been observed. The number for gray zone medicines is simply too overwhelming.[109]

Thus, according to the interviews conducted in Rio de Janeiro, one could think to create a specialized center to define whether the patient needs or not a specific medicine or treatment. For example, Brasilia would organize a center for the question of court orders for insulin pumps, which are medical devices used for the administration of insulin in the treatment of diabetes mellitus.

iii. Other types of improving access to medicines: People's Pharmacies

Not only in the State of Rio de Janeiro but all over Brazil, the Federal government has initiated a public-private partnership network and pharmaceutical assistance program called People's Pharmacy ("*Farmácia Popular*"), which is intended to ensure better access of the population to on-list medicines and via more affordable prices.[1] This works via money transfers with a fixed per capita amount from the Union directly to the municipalities, over to series of specific series of pharmacies to buy a fixed quantity of medicines.

Thus, prices in these pharmacies are purely symbolic and thus access to basic medicines improved. Rio de Janeiro State has 45 People's Pharmacies, out of which 7 are in Rio de Janeiro municipality. The scope of medicines sold in People's Pharmacies grew over the past years, including since 2006 medicines for diabetes and hypertension, since 2007 contraceptives, since 2010 vaccination against H1N1, dyslipidemia, rhinitis, asthma, Parkinson, Osteoporosis, and Incontinence glaucoma.[1] A current study question of this parallel approach, which is entire part of the SUS, to what extent it actually replaces traditional Pharmaceutical assistance programs of the Basic Component and whether small municipalities have more difficulties in using this approach as their purchasing options for small quantities are much more restricted.[110]

VI. Discussion

The present study examined reasons for the administrative failure to deliver on-list medicines. However, according to gray literature and interviews, lack of access to on-list medicines may also indicate several other possibilities, which have *not be examined in this study*.

A doctor can use different prescription forms when prescribing a drug: these can relate to the federal, state and municipal level. If the doctor uses the wrong form this can lead to the patient not receiving the medicine he/ she demands at the given level.

- Health authorities might deny the request for a prescription for which the doctor did not follow the therapeutic guidelines, either deliberately or inadvertently. The patient might then proceed to litigation.
- A lawsuit involving a single prescription calling for various medicines, some of which are included in an official list and some of which are not. However, in this case the entire request may proceed through litigation.
- Lawsuits demanding on-list medicines that are the result of problems in the definition of health priorities by the health authorities who inadequately respond to the epidemiological challenges of the population.

It is difficult, with the available information, to disentangle these alternative explanations and to define which percentage of claims would fall under each of these categories. It is however important to acknowledge this information as part of the causal explanations of the phenomenon of judicialization distorting access to on-list medicines.

Further, another important aspect of the discussion is the capacity to depict a national reality taking into account that there is a dilemma between individual rights and collective rights. It is true that the individual has a set of particularities and that individual rights should pervade for them. It is true also that the community is made up of individuals. However, regarding the right to health, accomplished through public health policies that fall within the Unified Health System, is it possible to respect all individual particularities? Knowing that resources are limited and needs unlimited, would it not be that a judge, when ensuring the right to a medicine to a single individual, representing a significant part of the total health budget available to the whole of a population, sacrifice the community for the sake of a single individual? These larger questions of equity and justice will be left open, and this study did not provide a basis to answer them. However, these issues need to be raised in the discussion of guaranteeing the right to health by

the judiciary, and the basic tenets of the Brazilian Unified Health System of universality, equity and integrality.

Table 3: Number of Health rights cases, per million population,[111] as of 2008

	Brazil	India	Indonesia	South Africa	Nigeria	Total
Regulation	0.03	0.05	0	0	0	0.08
Obligation	103.37	0.01	0	0.05	0	103.42
Total Health	119.21	0.10	0.012	0.07	0.07	119.46

Finally, it is important to consider that the phenomenon of judicialization not only appears in Brazil, but increasingly in other Latin American countries. An abundant literature exists for countries such as Colombia, and many administrations of other countries such as Uruguay, Costa Rica, Argentina and Chile have come to prepare this trend.[112] The table above[113] shows that Brazil is the leader in terms of judicialization of health rights. However, this trend is also appearing in other emerging countries such as South Africa, India, South Africa, Indonesia and better-off developing countries such as Nigeria.[114]

It is in the hands of all different actors of the health care systems to conceive long-lasting and cohesive responses to redirecting funds towards more equitable access to medicines and priority-setting, thus decreasing judicialization.

VII. Conclusion

The present study has provided an overview of the functioning mechanisms of pharmaceutical assistance activities at all administrative levels, in particular at the municipal level. Using a case study, the pattern of judicialization in Rio de Janeiro municipality has been examined.

It has further been assessed that, in many municipalities and States, the number of court orders for medicines that are not included in any of the official lists is surpassing the number of court order for on-list medicines. In both cases, it becomes clear that judicialization has been emerging as a costly trend since the 1990s. Even though not yet perceived by all municipalities, which might be due to strong regional differences of judicialization, this trend has come to affect the municipal level with particular strength, mainly due to the distortions of responsibilities that appear once a court order is formed with injunction, weighing first of all on municipalities. A series of management responses have been initiated that not only seek to reverse the trend of judicialization by creating a multi-stakeholder dialogue, but also by an attempt to shift responsibility away from the Judiciary back to the Executive. The most relevant illustration is the

administrative request system. Furthermore, other ways have been created to substantially improve access to medicines, in a universal approach.

However, the limits of these management responses have also been explored. What is currently the most important challenge are medicines of the so-called “gray zone”, medicines or services which are not revealing of any of the three administrative levels. It is in the hands of efficient pharmaceutical assistance management teams to come up with the right solutions to fill this “management vacuum”. Such solutions could be the inception of centralized mechanisms at the federal level to provide high-cost specialized components, such as insulin pumps. Furthermore, to reassess the regular financial flows between the three administrative levels: from the Federal District to States in bipartite commissions and to municipalities in tripartite commissions. These flows need to be adapted to trends of judicialization and ideally better take into account epidemiological, demographic and socio-demographic realities of each of the municipalities, which are as diverse as on a whole continent.

VIII. Recommendations and proposals for action

A. Better access to prevention programs and public access to medicines

1. Usefulness of prevention programs

As shown previously, most of the claimed medicines are for chronic conditions such as diabetes, cancer or hypertension. Brazil is indeed an emerging country is characterized by the epidemiological pattern of the “double burden” of both infectious diseases in the northern more impoverished zones and the “occidental” pattern of high prevalence of chronic diseases, causing a high financial burden to the health care system. However, as Brazil has only recently entered this transition: with one fourth (26.2%[115]) of Brazilians under the age of 15 (compared to the European Union average of 15.44%[116]), there is still a lot of potential for prevention programs to be effective in promoting healthier lifestyles among young people, including food, physical activity and the consumption of tobacco or alcohol. Doctors and health care professionals play a pivotal role in prevention and should be sensitive as a first interlocutor.

2. Access to low-cost medicines

First, the concept of people’s pharmacies has recently been introduced and shown to have an important impact on access to medicines, by allowing Brazilians of all social strata to access medicines at a purely symbolic price affordable even with low incomes. Guaranteeing the same

standards of safety and quality, this type of pharmacy should be extended to more areas of Brazil.

Second, Brazil has been engaging in a "pro-generics" policy since 1999[117] and promoting the systematic use of the generic version as a first choice in the presence of a brand medicine. This approach has led to important savings compared to what would have been spent purchasing the original drugs. The Brazilian government went as far as to claim the exceptional rule of "compulsory licensing" in the WTO agreement and thus able to produce the generic version of antiretroviral drugs.[118] In this offensive initiative, Brazil has become pioneer in its universal HIV/AIDS program.[119]

B. Functional improvements in administration

As has been outlined in this study, important deficiencies have been sources of unnecessary costs and have impeded access to essential medicines. According to Sueli Dallari[120], the most important deficiency lies within the procurement process, when administrations are often not able to purchase medicines at the best available price on the market in competitive conditions. Either monopolies exist, competitive bidding procedures as foreseen in the Constitution not respected, or purchasing quantities are too small. Another source of high costs in the procurement process are so-called emergency procedures, when - because of strict injunction clauses - medicines are purchased rapidly and at high costs for specific court orders. It would be useful to proceed to better training programs within purchasing units in the Health Secretariats at all administrative levels, so that a more coherent and anticipative purchasing process is elaborated, which proactively reacts to the incidence of court orders.

C. Promotion of multi-stakeholder dialogue

Only a strong multi-stakeholder campaign can be efficient in providing an efficient response to current trends of judicialization. Thus, it is important to actively promote multi-stakeholder dialogue as a first step and multi-stakeholder cooperation as a second step. Such multi-stakeholder collaborations, if institutionalized in committees and other representations, are then capable of proposing plans of actions which can be endorsed by Parliament and Government. It is also important to better inform all different stakeholders about the high costs of judicialization and its negative impact on health equity.

This could be achieved by organizing information and communication campaigns illustrating the distorting budget consequences of judicialization are illustrated, for example of all the different steps of a court order, including the costs of the doctor who prescribes, the lawyer seized by the

non-receiving end, the Court issuing the decision with all preparative steps, and the cost of the medicine itself, when purchased in non-competitive conditions. The final cost would be exponentially higher than in the conventional way when the patient acquires that medicine in the pharmacy.

D. Better monitor judicialization

Taking into account first of all that neither a national assessment of the phenomenon of judicialization exists but that even at the municipal and State level there are still many incoherencies in the assessment of this phenomenon, one of the urging proposals for action would be the implementation of parameters that could be introduced for streamlining and standardizing judicial performance in the supply of medicines, with regard to the State's and municipality's duty to supply medicines to the population.[121]

Specifically, in 2011 a multidisciplinary team with wide-ranging experience of judicialization has developed a manual[122] that establishes 30 indicators considered essential to better understand the demand for medicines through the Courts. This study –which used the State of Rio de Janeiro as amodel - generated indicators that could serve as a basis for better monitoring and evaluating the interactions between the citizen, the SUS and the justice system with the goal to ensure better access to high quality and safe medicines by the population.

The main objective of the project is not only identify problems but to create conditions for federal, state and municipal managers, judges, health and law professionals to act, favoring the development of strategies, tools and mechanisms for the improvement of Pharmaceutical Care and to reduce the intensity of lawsuits. [123]

The 30 indicators are classified in four mayor categories: 1) socio-demographic profile of the claimant and population, 2) characteristics of the lawsuit filing (time, density of lawsuits per inhabitant etc) 3) medico-sanitary characterization of the lawsuit and 4) politico-administrative characteristics of lawsuits (executive, administrative and economic competences of Public Administration). With regard to the present study, the politico-administrative type of indicator could be the most relevant one.

This manual should be rapidly made mandatory in all parts of Health Administration and the Judiciary, and lead to the establishment of data tables, which could then allow to provide a better picture of judicialization and possible causes at the municipal or State level. This could

also lead to more robust comparisons between areas, and allow us to produce an aggregate nation-wide assessment of judicialization.

IX. Annex

1. Abstracts in English, French and Portuguese

Abstract in English language

A possible combination of the lack of access to medicines and citizens' increased awareness of their possibility to use the justice system to pursue their constitutional right to health, has led to an escalating number of lawsuits in Brazilian Courts since the end of the 1990s.

The **objective** of this study is to assess challenges that municipalities, the municipality of Rio de Janeiro in particular, encounter in the implementation of pharmaceutical assistance programs, when facing an increasing demand for on-list medicines that should be regularly provided.

Methodology: The form of a descriptive study was used, including quantitative results mostly from an in-depth literature review in Brazilian and international publications and official data retrieved at the Municipal Health Secretariat level. Qualitative information and evaluations of the phenomenon were also retrieved from this literature review, in complement to interviews and correspondence with experts.

Results: Firstly, the impact of an increasing number of court orders at the municipal level was assessed by quantifying and qualifying this trend. Secondly, it was evaluated to what extent judicialization affects the regular cycle of pharmaceutical assistance activities, which is already characterized by a series of irregularities. Finally, existing management responses to this problem will be identified and evaluated, and recommendations formulated.

Discussion: Not only efficient management responses alone will not revert the trend of judicialization, as next to the Administration and the Courts many more actors of the unified health system (SUS) are implied in this trend. Further, lack of access to on-list medicines may also indicate several other possibilities inadequacies than inadequacies in the delivery of on-list medicines by the Administration.

Key words: *Right to health, judicialization, essential medicines, list of essential medicines, REMUNE, RENAME, lawsuits, court orders, pharmaceutical policy, pharmaceutical assistance, medicines procurement, federal or state or municipal competence*

Louisa Stüwe
Master of Public Health
EHESP

Résumé en français

Dans un contexte marqué par une meilleure connaissance des citoyens de leurs droits constitutionnels, les problèmes liés au manque d'accès aux médicaments au Brésil ont favorisé un recours croissant aux poursuites judiciaires depuis la fin des années 1990.

Dans cette perspective, **l'objectif** de cette étude est d'évaluer les défis que les municipalités, en particulier la ville de Rio de Janeiro, rencontrent dans la mise en oeuvre des programmes d'assistance pharmaceutique, face à une demande croissante de médicaments inclus dans la liste des médicaments censés être régulièrement fournis.

Concernant la **méthodologie**, cette étude s'appuie sur des résultats quantitatifs et objectifs émanant pour la plupart d'une revue de littérature et recherche documentaire ou de données officielles obtenues auprès du Secrétariat municipal de la santé de Rio de Janeiro. Les résultats qualitatifs et les interprétations proposées reposent ainsi sur les observations de cette même revue, d'une série d'interviews menés sur le terrain ainsi que de la correspondance continue avec les experts.

En ce qui concerne les **résultats,** l'impact d'un nombre croissant de décisions de justice au niveau municipal a été évalué, en quantifiant et qualifiant cette tendance dans un premier temps. L'impact de la judiciarisation sur le cycle régulier des activités d'assistance pharmaceutiques a par la suite permis de mettre en évidence un ensemble d'irrégularités. Enfin, des propositions en matière de gestion au regard de ces résultats ont été établies et complétées par la formulation d'une série de recommandations.

En **discussion**, l'étude a montré que seules des réponses efficaces de gestion auront la capacité d'inverser la tendance de la judiciarisation étant donné qu'elle implique tous les acteurs du système de santé. En outre, il est également apparu que le manque d'accès aux médicaments inclus dans les listes n'est pas uniquement lié aux insuffisances et irrégularités dans la fourniture de médicaments de la part de l'Administration.

Mots clés: *droit à la santé, judiciarisation, médicaments essentiels, liste des médicaments essentiels, REMUNE, RENAME, poursuites, ordonnances judiciaires, politique pharmaceutique, assistance pharmaceutique, achat de médicaments, compétences fédérale, fédérée ou municipale.*

Louisa Stüwe
Master of Public Health
EHESP

Resumo em Português

A judicialização dos medicamentos incluídos nas listas de medicamentos essenciais nos municípios brasileiros: uma investigação sobre a resolutividade do programa de assistência farmacêutica do Sistema Único de Saúde (SUS)

O aumento crescente do número de processos judiciais nos tribunais brasileiros desde o final da década de 1990 pode ser o resultado de uma possível combinação da falta de acesso a medicamentos e o aumento da informação aos cidadãos da sua possibilidade de usar o sistema judiciário para alcançar o seu direito constitucional à saúde. Foram cerca de 241.000 ações de saúde no ano de 2011 em todo o Brasil, sendo que a maior parte estava concentrada nos estados mais desenvolvidos. As ordens judiciais para o fornecimento de medicamentos são de aplicação imediata e exigem recursos consideráveis e, como os orçamentos destinados à saúde são limitados e pré-determinados, de acordo com a lei, com pelo menos um ano de antecedência, a judicialização – considerada uma tendência cara e de rápido crescimento - implica que os fundos destinados à saúde sejam realocados e que os planejamentos para a saúde sejam redesenhados nos três níveis administrativos desse Estado Federal (o nível nacional, estadual e municipal).

O objetivo deste estudo é avaliar os desafios que os municípios, particularmente o município do Rio de Janeiro, enfrentam na implementação de programas de assistência farmacêutica, diante de uma demanda crescente para os itens da lista de medicamentos essenciais que devem ser fornecidos regularmente para a população.

Presumiu-se que uma tendência crescente da judicialização ao nível municipal alteraria a resolutividade do programa de assistência farmacêutica do Sistema Único de Saúde (SUS) no fornecimento de medicamentos presentes nas listas.

O método escolhido para o estudo foi em formato descritivo, utilizando os resultados quantitativos e objetivos obtidos principalmente de uma profunda pesquisa bibliográfica, em publicações brasileiras e internacionais, e de dados oficiais obtidos da Secretaria Municipal de Saúde do Municipio do Rio de Janeiro. As informações qualitativas e as avaliações subjetivas do fenômeno, foram recuperadas a partir desta revisão da literatura, bem como a partir de entrevistas realizadas em diferentes estados brasileiros e através de correspondência de seguimento com os especialistas da área.

Primeiramente, o impacto do número crescente de ordens judiciais no nível municipal foi avaliado através uma quantificação e qualificação desta tendência. Em segundo lugar, foi avaliada como uma judicialização afeta o ciclo regular das atividades da assistência farmacêutica, que já é caracterizada por uma série de irregularidades. Finalmente, foram identificadas e avaliadas as respostas da gestão existentes para este problema, e foram formuladas algumas recomendações.

Palavras-chave: *Direito à saúde, judicialização, medicamentos essenciais, lista de medicamentos essenciais, REMUME, RENAME, ações judiciais, ações judiciais liminares, política de assistência farmacêutica, compras de medicamentos, competência federal, estadual ou municipal.*

2. List of tables and figures

Figures:

Tables:

3. Interview list and schedule

A. First field visit

Sao Paulo:
12.12.2011: Dr. Sueli Dallari, Health Law Professor at Sao Paulo University's School of Public Health 12.12.2011: Ana Luiza Chieffi, Advisor of the Pharmaceutical Assistance program at Sao Paulo's State Health Secretariat
13.12.2011: Dr. Alvaro Attalah, Director of Cochrane Center Brazil

Belo Horizonte, Minas Gerais
14.12.2011: Dr. Daniel Faleiros, Head of High-Cost Medicines Unit at the State Health Secretariat of Minas Gerais, Brazil
14.12.2011: Dr. Augusto Afonso Guerra Jr, Professor at Federal University of Minas Gerais (UFMG)

Brasilia:
15.12.2011: Dr. Alethele de Oliveira Santos, Advisor at CONASS (National Council of State Health Secretariats)
16.12.2011: Fernanda Terrazas, Advisor at CONASEMS (National Council of Municipal Health Secretariats)
16.12.2011: Luis Felipe Galeazzi Franco, Legal Department, Ministry of Health of Brazil

Rio de Janeiro:
19.12.2011: Dr. Denizar Vianna, Professor at State University of Rio de Janeiro)

Porto Alegre:
20.12.2011: Dr. Paulo Picon, Professor at Federal University of Rio Grande do Sul (UFRGS) and team at University Hospital
20.12.2011: Paulo Jardim and Patrícia Bernadi Dall'Acqua at State Solicitor's Office of Rio Grande do Sul

20.12.2011: Dr. André Luiz de Abreu Porto of the Pharmaceutical Assistance Policy Coordination Center of the State of Rio Grande do Sul

20.12.2011: Eugênio Couto Terra, Judge at Public Administration branch of the *Tribunal de Justiça* of Rio Grande do Sul

20.12.2011: Francisco Donizete Gomez, Judge at Regional Federal Tribunal in Porto Alegre

B. Second field visit

Rio de Janeiro:

16.4.2012 – 20.4.2012: Dr. Denizar Vianna, Professor at State University of Rio de Janeiro

18.4.2012: Dr. Roselee Pozzan, Professor at State University of Rio de Janeiro and Dr. Luciana Bahia, Endocrinologist and Researcher at State University of Rio de Janeiro

18.4.2012: Michelle Quarti Machado da Rosa, Scientific Coordinator at State University of Rio de Janeiro

19.4.2012: Rondineli Mendes and team at the Municipal Health Secretariat of Rio de Janeiro

4. Research collaboration agreement

Paris, 29 de abril de 2012

Acordo de Cooperação entre Secretaria Municipal de Saúde e Defesa Civil do Rio de Janeiro e École des Hautes Études en Santé Publique

Exmo. Secretário de Saúde do Município do Rio de Janeiro Dr. Hans Fernando Rocha Dohmann

Eu, Louisa Stüwe, pesquisadora e mestranda em Saúde Pública da École des Hautes Études en Santé Publique (EHESP), estou desenvolvendo pesquisa intitulada "Judicialization of on-list medicines in Brazil: Examining inadequacies of the pharmaceutical assistance program of the National Public Health System (SUS / Sistema Único de Saúde) Case study: Municipality of Rio de Janeiro". Esta pesquisa é parte integrante do Master International de Santé Publique da EHESP, com previsão de

conclusão para junho de 2012.

Gostaria de solicitar acesso aos dados de utilização de medicamentos do Programa de Atenção Básica, Programa de Medicamentos Estratégicos, Programa de Medicamentos de Dispensação Especial e medicamentos dispensados por via judicial na Secretaria Municipal de Saúde e Defesa Civil do Rio de Janeiro (SMSDC-RJ), nos últimos três anos.

Ratifico que o uso destas informações estará restrito a dissertação de mestrado do Master International de Santé Publique da EHESP.

Atenciosamente

Louisa Stüwe

Louisa.stuewe@eleve.ehesp.fr

École des Hautes Études en Santé Publique (EHESP)

5. Original Survey

Questionário para Dissertação de Mestrado: A judicialização dos medicamentos incluídos nas listas de medicamentos essenciais nos municípios brasileiros: uma investigação sobre a resolutividade do programa de assistência farmacêutica do Sistema Único de Saúde (SUS)

Louisa Stüwe
Mestrado de Saúde Publica
EHESP Escola Francesa da Saúde Publica

Por favor, tente responder a todas as perguntas abaixo. Mesmo que você não tenha dados precisos. Para responder às perguntas, por favor, tente descrever sua percepção da situação.

I. Informações sobre o entrevistado

1) Nome e formação acadêmica

2) Órgão administrativo / agência

3) Função atual neste órgão

4) Município / Estado

5) Quantos anos de experiência?

6) Qual é a abrangência geográfica de cobertura das ações do seu órgão administrativo?

II. Relação municipal de medicamentos essenciais (REMUME)

1) Quantos itens estão incluídos na REMUME?

http://www.ensp.fiocruz.br/portal-ensp/judicializacao/pdfs/288.pdf

2) Qual é o item de menor custo e qual é o item de maior custo? Em quais quantidades são adquiridos estes itens?

3) A quantidade destes itens tem correlação com as quantidades adquiridas por outros municípios?

4) Com qual periodicidade é realizada a revisão da REMUME? Há algum tipo de ocorrência extra que provoque a revisão da REMUME? Existe uma comissão técnica responsàvel pela criação, manutenção e atualização da REMUME?

5) Se existente, essa comissão conta com representantes de quais orgãos? A comissão conta com membros externos, consultores, etc? Quais?

6) A REMUME se estabelece em cooperação com outros municípios? Quais?

7) Quais foram os gastos, no ano anterior para aquisição dos medicamentos da atenção primária no seu municipio com recursos do município, do estado e da União?

8) É possível que o seu município forneça medicamentos que são do nível estadual ou federal? Isto acontece frequentemente? E vice-versa?

10) Qual a sua opinião a respeito da existência de listas diferentes de medicamentos nos três níveis administrativos?

III. Aquisição de medicamentos

1) Quais são as outras entidades envolvidas no processo de aquisição dos medicamentos no seu município?

2) Quem seleciona o tipo e a quantidade de medicamentos adquiridos? Quais são os critérios utilizados para decidir o que será adquirido (por exemplo, é baseado no perfil epidemiológico da população, de onde estes dados vêm)?

3) Qual é o tempo médio de duração do processo de aquisição, desde a solicitação da compra de medicamento, realizada pela área técnica demandante, até o recebimento do mesmo no almoxarifado?

4) Existe outra forma de aquisição de medicamentos que não seja por meio do processo de licitação?

5) Liste quais são os problemas mais comuns que ocorrem nos processos de aquisição de medicamentos.

6) Quais são as soluções identificadas para resolver estes problemas?

IV. A judicialização na demanda por medicamentos

1) Qual é a proporção dos medicamentos incluídos nas listas (REMUME ou outras) que fazem parte das demandas judiciais?

2) Os medicamentos solicitados judicialmente foram solicitados isoladamente ou dentro de um "pacote" maior de medicamentos?

2) Na sua opinião, a proporção de demandas judiciais de medicamentos pertencentes as listas é maior do que a demanda de medicamentos fora das listas?

3) Quais são as razões de não se entregar por via administrativa todo e qualquer medicamento solicitado pela população? Em seguida qual é a opinião dos juízes na visão dos gestores?

4) Como funciona o processo para aquisição emergencial de medicamentos que fazem parte das demandas judiciais, as quais o juiz tem respondido favoravelmente? Qual o impacto que estas demandas geram no orçamento do município?

5) Quanto aos medicamentos não incluídos na lista, eles foram incluídos após a sua judicialização? Em caso afirmativo, você pode fornecer exemplos?

6) Em termos globais, como é que a judicialização afeta o processo de aquisição de medicamentos?

V. Documentos solicitados

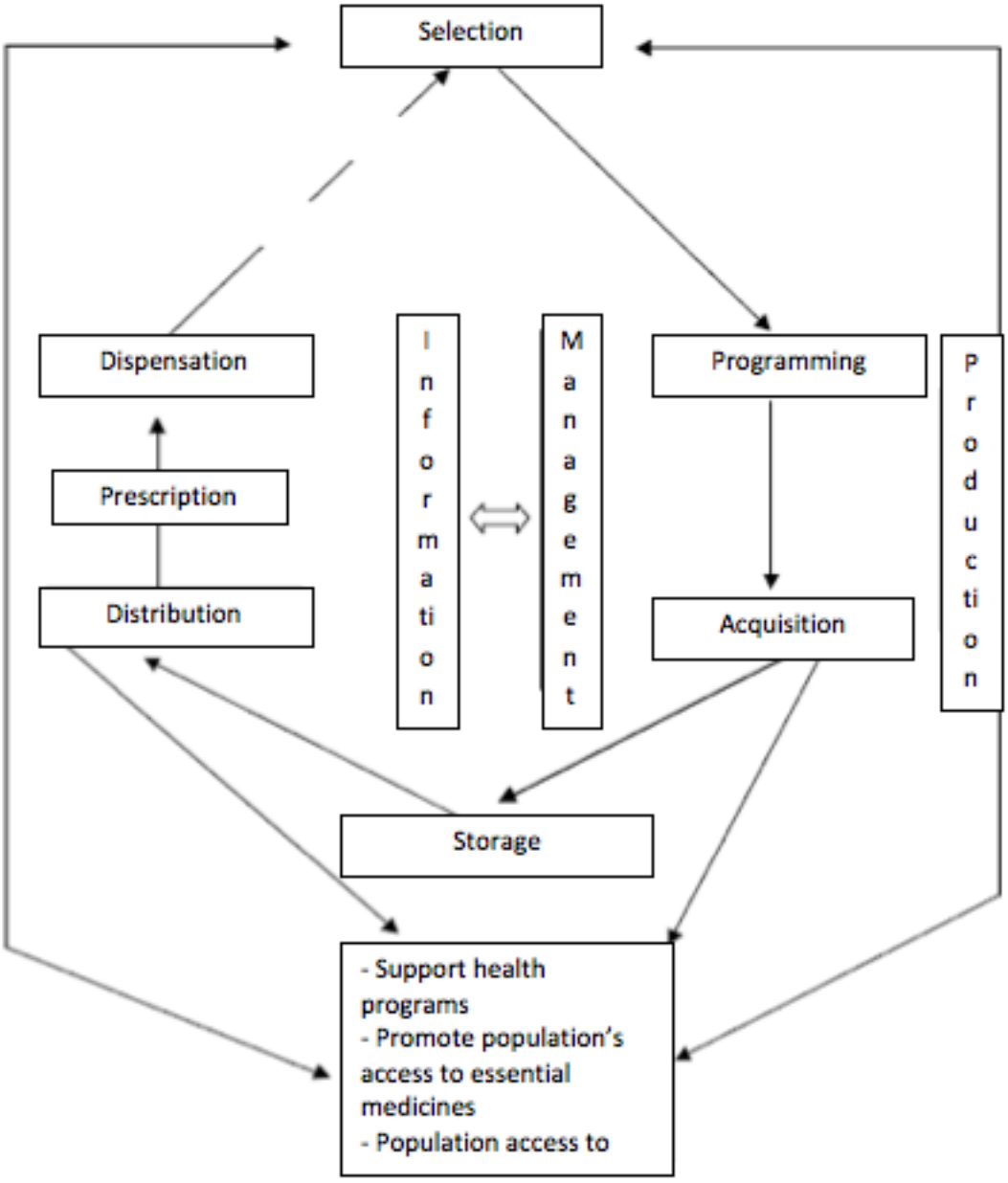
1) Por favor, forneça uma cópia / link da relação municipal de medicamentos essenciais.

2) Além da Lei de Licitação (Lei 8666/ 93) vigente no Brasil, bem como as normas preconizadas pela ANVISA para medicamentos, por favor, forneça uma cópia / link de outros documentos / diretrizes que regulam o processo de aquisição e distribuição de medicamentos no seu município / as atividades das farmácias.

3) Se acessível, forneça referências a importantes decisões judiciais que têm afetado o procedimento da aquisição dos medicamentos no seu município

6. Material in illustration and detailing of Master thesis

Figure 4: Pharmaceutical Assistance Activities



124

Figure 3: Administrative Request System

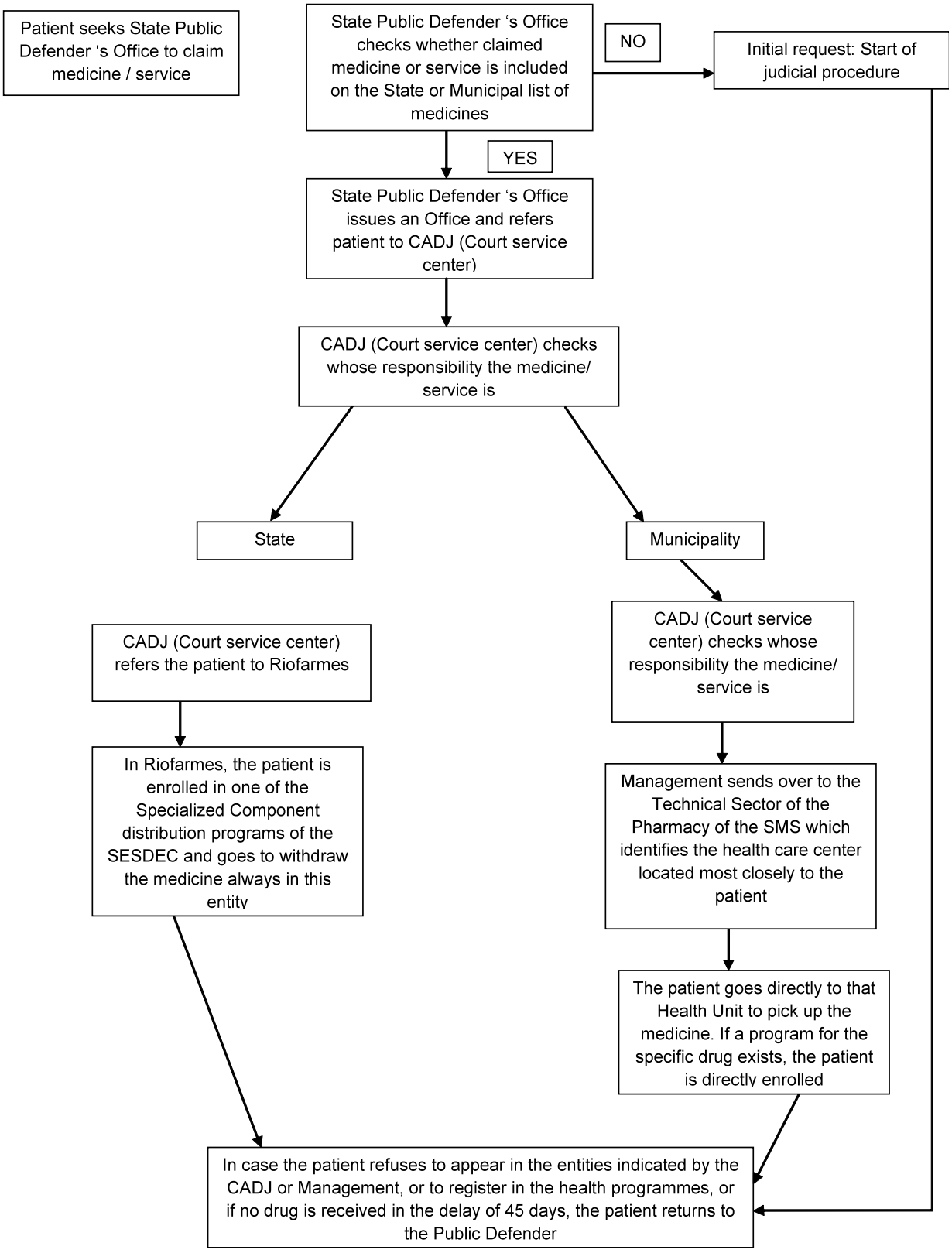


Table 4: Court Orders Received in Municipal Health Secretariat of Rio de Janeiro between January and July 2011

	JAN	FEV	MAR	ABR	MAI	JUN	JUL	TOTAL
MEDICAMENTOS	81	65	36	49	38	25	104	398
INSUMOS	7	10	7	9	16	6	15	70
MED. + INSUMOS	7	10	3	8	6	6	15	55
MED. + INSUMOS + PERM.	-	2	-	-	-	-	1	3
PERMANENTE	4	3	4	5	3	-	1	20
PERMAN.+ MEDICAMENTOS	1	-	-	1	-	-	1	3
PERMAN.+ INSUMOS	-	1	2	-	-	-	-	3
CÂMARA HIPERBÁRICA		3	1	-	-	-	4	8
OXIGÊNIO	-	1	1	-	3	4	3	12
OXIGÊNIO + MEDIC.	5	-	-	-	2	1	1	9
OXIGÊNIO + INSUMOS	-	1	-	-	-	-	-	1
INTERNAÇÃO	8	15	8	4	12	4	10	61
CIRURGIA/EXAMES	1	1	2	4	2	3	4	17
AMBULÂNCIA	1	1	-	-	1	1	-	4
HOME-CARE	-	-	1	-	-	2	1	4
EXCEPCIONAL	7	13	4	9	4	7	5	49
DEFENSORIA	3	5	13	12	2	8	16	59
T O T A L	125	131	82	101	89	67	181	776

X. List of References

1. Acero, Liliana or human stem cells research, Genomics, Society and Policy, 10/11, Vol.6, No.3 pp.15-31, Link: http://www.hss.ed.ac.uk/genomics/V6N3/documents/AceroFINAL1July2011_001.pdf, accessed March 12, 2012
2. Alves, Alessandra Vanessa, Atuação da consultoria jurídica do ministerio da saúde nas demandas judiciais da saúde, Coordenadora Geral de Assuntos Jurídicos, AGU: From CDJU – Coordenação de Demanda Judicial, Link: http://www.cnj.jus.br/images/programas/forumdasaude/papeldaconjurnasacoesdesaude.pdf, accessed May 12, 2012
3. Amaral de Ávila Machado, Marina; Acúrcio, Francisco de Assis; Brandão, Cristina Mariano Ruas; Faleiros, Daniel Resende; Guerra Júnior, Augusto Afonso; Cherchiglia, Mariangela Leal; Andrade, Eli Iola Gurge, Judicialização do acceso de medicamentos no Estado de Minas Gerais, Brasil, Rev Saúde Pública 2011;45(3):590-8
4. Andrade, Eli Iola Gurge; Machado, Carlos Dalton; Faleiros, Daniel Resende; Szuster, Daniele Araújo Campos, Guerra Júnior, Augusto Afonso; Dias da Silva, Grazielle; Cherchiglia, Mariangela Leal; Acúrcio, Francisco de Assis, A judicialização da saúde e a politica nacional de assisência farmacêutica no Brasil: gestão da clinica e medicalização da justiça, Rev Med Minas Gerais 2008; 18(46 4 Supl 4): 46-50
5. Araújo LU, Albuquerque KT, Kato KC, Silveira GS, Maciel NR, Spósito PÁ, Barcellos NM, Souza J, Bueno M, Storpirtis S., Generic drugs in Brazil: historical overview and legislation, Rev Panam Salud Publica. 2010 Dec;28(6):480-92. Link: http://www.ncbi.nlm.nih.gov/pubmed/21308175, accessed June 5, 2012
6. Barroso, Luís Roberto, Da falta de efetividade à judicialização excessiva: Direito à saúde, fornecimento gratuito de medicamentos e Parâmetros para a atuação judicial, Trabalho desenvolvido por solicitação da Procuradoria-Geral do Estado do Rio de Janeiro. Pesquisa e debates desenvolvidos no âmbito do Instituto Idéias,dos quais participaram os Professores Ana Paula de Barcellos e Cláudio Pereira de Souza Neto.
7. Bassette, Fernanda, RS reúne metade das ações judiciais de saúde - O Estado de Sao.Paulo, Link: http://www.estadao.com.br/noticias/impresso,rs-reune-metade-das-acoes-judiciais-de-saude,712418,0.htm, accessed February 6, 2012
8. Bassette, João, Adriana Petryna, Alex Gertner, Joseph J. Amon, Paulo D. Picon, Judicialização do direito à saúde no Brasil, in: Tânia Margarete Mezzomo Keinert, Silvia Helena Bastos de Paula, José Ruben de Alcântara Bonfim, As ações judiciais no SUS e a promoção do direito à saúde, Instituto de Saúde, São Paulo, 2009, p.147f., Link: http://www.isaude.sp.gov.br/smartsitephp/media/isaude/file/acoesjudiciais.pdf, accessed March 2, 2012
9. Biehl, João, Right to Health Litigation, Department of Anthropology, Woodrow Wilson School of Public and International Affairs, Link: http://joaobiehl.net/global-health-research/right-to-health-litigation, accessed March 12, 2012
10. Biehl, João, Petryna, Adriana, Gertner, Alex, Amon, Joseph J., Picon, Paulo D., Judicialização do direito à saúde no Brasil, in: Tânia Margarete Mezzomo Keinert,

Silvia Helena Bastos de Paula, José Ruben de Alcântara Bonfim, As ações judiciais no SUS e a promoção do direito à saúde, Instituto de Saúde, São Paulo, 2009, p.147f., Link: http://www.isaude.sp.gov.br/smartsitephp/media/isaude/file/acoesjudiciais.pdf, accessed Mary 1, 2012

11. Bomfim, Regina Lúcia Dodds, Agenda Unica de Saúde: A busca do acesso universal e a garantia do direito a saúde, Universidade do Estado do Rio de Janeiro, Instituto de Medicina Social, 2008.
12. Brito, Renata Janaina de Sousa, A judicialização do direito a saúde: Uma revisão bibliográfica da produção cientifica nacional, Universidade de Brasília, 2011. (not officially published)
13. Chieffi A.L., Barata R.B., Judicialização da política pública de assistência farmacêutica e eqüidade. Cad. Saúde Pública 2009 Ago; 25(8):1839-1849. Santos L. SUS: contornos jurídicos da integralidade da atenção à saúde. Radis Comunicação em Saúde 2006; (49). Link: http://www.ensp.fiocruz.br/radis/49/web-02.html, accessed March 23, 2012
14. Collucci, C., Triplicam as ações judiciais para obter medicamentos. Folha de São Paulo, São Paulo, 01 de janeiro de 2009. Link: http://www.sindifarmajp.com.br/noticias.php?not_id=765, accessed January 1, 2012
15. De Mello, Rodrigo Gaspar, Fornecimento de medicamentos pelo poder publico e a competência da Revista da justiça federal, SJRJ, Rio de Janeiro, 2010, p. 139-150
16. Department of Health of Rio de Janeiro database of 2011, medicines obtained via Judiciary
17. Diniz, Debora, Aborto e inviabilidad fetal: el debate brasileño, Cad. Saúde Pública vol.21 no.2 Rio de Janeiro Mar./Apr. 2005, Link: http://www.scielosp.org/scielo.php?pid=S0102-311X2005000200032&script=sci_arttext, accessed April 1, 2012
18. Diniz, Debora, Medeiros, Marcelo, Schwartz, Ida Vanessa D. Consequências da judicialização das políticas de saúde: custos de medicamentos para as mucopolissacaridoses, Cad. Saúde Pública, Rio de Janeiro, 28(3):479-489, mar, 2012
19. Sacco, Renata Dos Anjos, judicialização e equidade no tratamento da hepatite C: estudo do caso sobre o tratamento com interferona alfa em um serviço de referencia do SUS em Porto Alegre, RS, UFRGS, Faculdade de medicina, Porto Alegre, 2009
20. Ferraz, Octavio Luiz Motta, Right to health litigation in Brazil: Why are collective suits so hard to enforce? , University of Warwick, School of Law, Link: http://www.escr-net.org/usr_doc/Ferraz_-_Implementing_the_Right_to_Health_in_Brazil.pdf, accessed March 27, 2012.
21. Ferraz, Octavio Luiz Motta, Right to Health Litigation in Brazil: legal framework, jurisprudence, social impact and future perspectives, World Bank Project, Final Draft, July 2011
22. Ferraz, Octavio Luiz Motta, The right to health in the courts of Brazil: worsening health inequities?, Health and Human Rights: An International Journal 11/2 (2009),

pp. 33–45. Link: http://www.hhrjournal.org/index.php/hhr/article/viewArticle/172, accessed March 12, 2012

23. Figueiredo, Tatiana de Aragão; Garcia Serpa Osorio-de- Castro, Claudia; Analysis of medicines dispensed by court order in the court of Rio de Janeiro: The application of scientific evidence in the decision-making process, Ministry of Health and Oswaldo Cruz Foundation, presented at HTAi 2011, Link: http://www.htai2011.org/documentos/944%20VLEP.pdf, accessed March 30, 2012
24. Figueiredo, Tatiana de Aragão; Garcia Serpa Osorio-de- Castro, Claudia; Pepe, Vera Lúcia Edais, Um enfoque sanitário sobre a demanda judicial de medicamentos, Physis Revista de Saúde Coletiva, Rio de Janeiro, 20 [1]: 101-118, 2010
25. Figueiredo, Tatiana de Aragão. Análise dos medicamentos fornecidos por mandado judicial na Comarca do Rio de Janeiro: A aplicação de evidências científicas no processo de tomada de decisão [dissertação]. Rio de Janeiro (RJ): Escola Nacional de Saúde Pública Sérgio Arouca. Fundação Oswaldo Cruz; 2010. Link: http://bvssp.icict.fiocruz.br/pdf/25584.pdf, accessed accessed April 21, 2012
26. Fleury, Sonia. "A questão democrática na Saúde". In: FLEURY, Sonia (Org.) Saúde e Democracia: a luta do Cebes. São Paulo: Lemos Editorial, 1997. In: Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.24
27. Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.
28. Geocze, Luciana et al. Qualidade de vida e adesão ao tratamento anti-retroviral de pacientes portadores de HIV. Rev. Saúde Pública [online]. 2010, vol.44, n.4 [cited 2012-06-02], pp. 743-749
29. Gloppen, Siri, Litigation as a strategy to hold governments accountable for implementing the right to health, Health and Human Rights: An International Journal 10/2 (2009), pp. 21–36. Link: http://hhrjournal.org/index.php/hhr/article/view/79/164, accessed February 9, 2012
30. Iunes, Roberto, Sarti, Flavia M., Coelho Campino, Antonio Carlos, Diaz, Maria Dolores M., Sierra, Ricardo: Assessing financial protection and equity under the Brazilian national health care system, Inter-American Development Bank, 2009
31. Lopes, L. C., Barberato Filho, S, Polimeno, N.C., Costa, A.C., Naffah Filho, M., Correa, M.C., Osorio-de-Castro, C.G.S. Medicamentos antineoplásicos e ações judiciais: contribuição para o modelo de assistência farmacêutica no SUS. In: Seminário: Programa de Pesquisa para o Sistema Único de Saúde (PPSUS-SP) 2004-2007, 2008, São Paulo. Relatório de resultados dos projetos de pesquisa/Seminário PPSUS-SP, 2008.
32. Loyola, Maria Andréa. Medicamentos e saúde pública em tempos de AIDS: metamorfoses de uma política dependente. Ciênc. saúde coletiva, Rio de Janeiro, 2011. Link: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1413-81232008000700027&lng=en&nrm=iso, accessed March 1, 2012

33. De Macedo, Eloisa Israel, Lopes, Luciane Cruz, Barberato-Filho, Silvio, A technical analysis of medicines request-related decision making in Brazilian courts, Rev Saúde Pública 2011;45(4)
34. Marques, Silvia Badim. Judicialização do direito à saúde. Rev. Direito Sanit. São Paulo, v. 9, n. 2, 2008. Link: http://www.revistasusp.sibi.usp.br/scielo.php?script=sci_arttext&pid=S1516-41792008000200005&lng=pt&nrm=iso, accessed March 17, 2012
35. Marques, Silvia Badim, A relação do sistema jurídico e do sistema político na garantia do direito social à assistência farmacêutica: o caso do Estado de São Paulo, Universidade de São Paulo, Faculdade de Saúde Pública, 2005
36. Messeder AM, Osorio-de-Castro CGS, Luiza VL. Mandados judiciais como ferramenta para garantia do acesso a medicamentos no setor público: a experiência do Estado do Rio de Janeiro, Brasil. Cad Saude Publica 2005; 21(2):525-534.
37. Ministério da Saúde, Política Nacional de medicamentos, Ministério da Saúde, Secretaria de Políticas de Saúde, Departamento de Formulação de Políticas de Saúde, Brasília, maio de 2001, Link: http://bvsms.saude.gov.br/bvs/publicacoes/politica_medicamentos.pdf, accessed February 28, 2012
38. Ministério da Saúde, Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Departamento de Assistência Farmacêutica e Insumos Estratégicos, Assistência farmacêutica na atenção básica: instruções técnicas para sua organização – 2. ed. – Brasília : Ministério da Saúde, 2006. 100 p.: il. – (Série A. Normas e Manuais Técnicos), Link: http://www.ensp.fiocruz.br/portal-ensp/judicializacao/pdfs/283.pdf, accessed May 2, 2012
39. Okchstein Kelbert, Fabiana, A necessária ponderação entre a teoria da reserva do possível e a proteção do núcleo essencial dos direitos fundamentais, Mestrado em Direito, Faculdade de Direito, PUCRS, 2008 (not officially published)
40. De Oliveira, Vanessa Elias, Direito a saude em um mundo de escassez: Judiciário e Medicamentos no Estado de São Paulo, Universidade Federal do ABC (UFABC), 2010
41. Ombaka, Eva, Current status of medicines procurement, American Journal of Health-System Pharmacy March 1, 2009 vol. 66 no. 5 Supplement 3 p. 20-28, Link: http://www.ajhp.org/content/66/5_Supplement_3/s20.full, accessed March 12, 2012
42. Pepe, Vera Lúcia Edais, Figueiredo, Tatiana de Aragão, Simas. Luciana , Garcia, Claudia, Osorio-de-Castro, Serpa, Ventura, Míriam, A judicialização da saúde e os novos desafios da gestão da assistência farmacêutica, Ciência & Saúde Coletiva, 15(5):2405-2414, 201
43. Pepe, Vera Lucia Edais e Ventura, Miriam (org.); com a colaboração de Claudia Garcia Serpa Osorio-de-Castro. Instituto de Comunicação e Informação Científica e Tecnológica Biblioteca de Saúde Pública, Indicadores de avaliação e monitoramento das demandas judiciais de medicamentos, Manual 2011. Rio de Janeiro: Fundação Oswaldo Cruz, Escola Nacional de Saúde Pública Sergio Arouca, 2011.
44. Pepe, Vera Lúcia Edais; Figueiredo, Tatiana de Aragão; Brambati Sant'ana, João Maurício; dos Reis de Souza, Vanessa; Simas, Luciana; Garcia Serpa Osorio-de-

Castro, Claudia; Characterization of lawsuits for the supply of essential medicines in the State of Rio de Janeiro, Brazil, National School of Public Health, Oswaldo Cruz Foundation, presented at HTAi 2011, Link: http://www.htai2011.org/documentos/911%20VP.pdf, accessed June 1, 2012

45. Pepe, Vera Lúcia Edais et al. Caracterização de demandas judiciais de fornecimento de medicamentos „essenciais no Estado do Rio de Janeiro, Brasil. Cad. Saúde Pública. Rio de Janeiro, v. 26, n. 3, mar. 2010.
46. Pereira, Marco Aurélio, Programa Farmácia Popular e o Plano de Ações de Enfrentamento às Doenças Crônicas Não Transmissíveis, Presentation delivered during the 4th Pharmaceutical Assistance Forum of 2011 (VI Fórum Nacional de Assistência Farmacêutica), Link: http://portal.saude.gov.br/portal/arquivos/pdf/VI_Forum_Nacional_Assist_Farm.pdf, accessed February 12, 2012
47. Pereira, Januária Ramos; Santos, Rosana Isabel dos; Nascimento Junior, José Miguel do and Schenkel, Eloir Paulo. Análise das demandas judiciais para o fornecimento de medicamentos pela Secretaria de Estado da Saúde de Santa Catarina nos anos de 2003 e 2004. Ciênc. saúde coletiva [online]. 2010, vol.15, suppl.3, pp. 3551-3560. ISSN 1413-8123
48. Pessoa, Higor Rezende, Considerações sobre as decisões judiciais que concedem o fornecimento de medicamentos sem o devido registro na Agência Nacional de Vigilância Sanitária – ANVISA, 2011
49. Romero, Luiz Carlos. Judicialização das políticas de assistência farmacêutica: o caso do Distrito Federal. Textos para Discussão. Brasília, maio 2008. Link: http://www.senado.gov.br/conleg/textos_discussao.htm, accessed February 2, 2012.
50. Sant'Ana, Joao Mauricio Brambati, Pepe, Vera Lúcia Edais, Osorio-de-Castro, Claudia Garcia Serpa, Ventura, Miriam, Essencialidade e assistência farmacêutica: considerações sobre o acesso a medicamentos mediante ações judiciais no Brasil, Revista Panamericana de Salúd Publica, 29 (2), 2011.
51. Sant'ana, João Maurício Brambati; Pepe, Vera Lúcia Edais; Figueiredo, Tatiana de Aragão; dos Reis de Souza, Osorio-de- Castro, Claudia Garcia Serpa, Ventura, Miriam, Racionalidade terapêutica: elementos médico-sanitários nas demandas judiciais de medicamentos, Rev Saúde Pública 2011;45(4):714-21
52. Santos CC, Guimarães LG, Gonçalves SA. Estratégias para reorganização e otimização das atividades destinadas ao fornecimento de medicamentos demandados judicialmente contra a Secretaria de Estado de Saúde do Distrito Federal [monografia de especialização]. Brasília (DF): Faculdade de Ciências da Saúde, Universidade de Brasília; 2006.
53. Santos, Alethele de Oliveira, A abordagem de temas jurídicos na audiência pública da saúde no Supremo no Supremo Tribunal Federal, Fundação Oswaldo Cruz – Brasília, Programa de Direito Sanitário, 2010 (not officially published)
54. Dos Santos, José Sebastião, A via judicial para o acesso aos medicamentos e o equilíbrio entre as necessidades e desejos dos usuários, do sistema de saúde e da indústria, 2011 (not officially published)

55. Schincariol, Isabela, Manual traz indicadores judiciais de medicamentos, 16/04/2011, Link: http://www.ensp.fiocruz.br/portal-ensp/informe/site/materia/detalhe/24720, accessed May 8, 2012
56. Spedo, Sandra Maria, et al., O desafio da descentralização do Sistema Único de Saúde em município de grande porte: o caso de São Paulo, Brasil, Cad. Saúde Pública vol.25 no.8 Rio de Janeiro Aug. 2009, Link: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102, accessed February 6, 2012
57. Supremo Tribunal Federal (STF), Audiência Pública - Saúde, Link: http://www.stf.jus.br/portal/cms/verTexto.asp?servico=processoAudienciaPublicaSaude, accessed March 12, 2012
58. Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, March 2011
59. Terrazas, Fernanda Vargas, Os Impactos Da Judicialização Da Saúde No Orçamento Público Da Saúde: O Caso Do Município De São Paulo / The Impact Of Health Litigation On The Public Health Budget: The Case Of The City Of São Paulo (not officially published)
60. Ventura, Miriam; Simas, Luciana, Pepe, Vera Lúcia Edais, Schramm, Fermin Rolan, Judicialização da saúde, acesso à justiça e a efetividade do direito à saúde, Physis Revista de Saúde Coletiva, Rio de Janeiro, 20 [1]: 77-100, 2010
61. Vianna, Luiz Werneck, Burgo, Baumann Burgos. Entre princípios e regras: cinco estudos de caso de ações civis públicas. / Principles and rules: five case studies of class action suits in Brazil, Dados – Revista de Ciências Sociais 2005; 48(4): 777-843, Link: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0011-52582005000400003, accessed May 2, 2012
62. Vieira, Fabiola Sulpino and Zucchi, P., "Distorções causadas pelas ações judiciais à política de medicamentos no Brasil" ("Distortions to national drug policy caused by lawsuits in Brazil"), Revista de Saúde Pública 41/2 (2007), pp. 214–222
63. Vieira, Fabiola Sulpino, Ações judiciais e direito à saúde: reflexão sobre a observância aos princípios do SUS, Rev Saúde Pública 2008;42(2):365-9
64. Vieira, Fabiola Sulpino, Evolução dos Gastos do Ministério da Saúde com Medicamentos, Ministério da Saúde, Brasilia, 2007.
65. Virgílio, Afonso da Silva, Terrazas, Fernanda Vargas, Claiming the Right to Health in Brazilian Courts: The Exclusion of the Already Excluded?, Law & Social Inquiry Law & Social Inquiry, Volume 36, Issue 4, pages 825–853, Fall 2011, available at: http://onlinelibrary.wiley.com/doi/10.1111/j.1747-4469.2011.01252.x/references
66. Wang, DWL, Poder Judiciário e Politicas Publicas: participação democrática e equidade, Cadernos Gestão Publica e Cidadania, v. 54, 2009.
67. Ministry of Health: Aquisição de Medicamentos para Assistência Farmacêutica no SUS, Orientações Básicas, Ministério da Saúde, Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Brasília – DF, 2006, Link: http://portal.saude.gov.br/portal/arquivos/pdf/aquisicao_medicamentosfinal.pdf, accessed May12, 2012
68. Ministry of Health: Política nacional de medicamentos, Ministério da Saúde, Secretaria de Políticas de Saúde, Departamento de Atenção Básica. 2001. Brasília: 2001. Link: http://bvsms.saude.gov.br/bvs/publicacoes/politica_medicamentos.pdf, accessed May 9, 2012

69. National Agency for Sanitary Vigilence: Vigilância Sanitária e Licitação Pública, Agência nacional de Vigilância Sanitária, Brasília, Junho de 2003, Link: http://www.anvisa.gov.br/divulga/cartilha_licitacao.pdf, accessed March 27, 2012
70. Federal Prosecution: Intervenção Judicial na saúde pública, Panorama no âmbito da Justiça Federal e Apontamentos na seara das Justiças Estaduais, ADVOCACIA-GERAL DA UNIÃO CONSULTORIA JURÍDICA/ MINISTÉRIO DA SAÚDE, 2010 (not officially published)

XI. Websites

- WHO: http://www.who.int/en/
- WHO Essential Medicines: http://www.who.int/topics/essential_medicines/en/
- WHO data and statistics: http://www.who.int/research/en/
- Pan-American Health Organization (PAHO), WHO's Regional Offfice for the Américas): http://new.paho.org/index.php
- PAHO Essential Medicines: http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=1160&Itemid=327
- World Bank Statistics: data.worldbank.org/
- FMI (currency rates): http://www.imf.org/external/index.htm
- Brazilian Ministry of Health: http://portalsaude.saude.gov.br
- Brazilian National School of Public Health: http://www.ensp.fiocruz.br
- Brazilian Institute of Geography and Statistics: www.ibge.gov.br/english/
- National Justice Council: http://www.cnj.jus.br
- State Health Secretariat of Rio de Janeiro: http://www.saude.rj.gov.br/i
- SMSDC - Secretaria Municipal de Saúde e Defesa Civil (Municipal Health Secretariat of Rio de Janeiro): http://www.rio.rj.gov.br/web/smsdc/
- Secretaria do Estado de Saúde (State Health Secretariat of Rio de Janeiro): http://www.saude.rj.gov.br/
- Advocacia-Geral da União: http://www.agu.gov
- SciELO databases: http://www.scielosp.org/
- Brazilian Virtual Health Library: http://regional.bvsalud.org/php/index.php?lang=en
- JSTOR: http://www.jstor.org/
- Science Direct: http://www.sciencedirect.com/
- PubMed: http://www.ncbi.nlm.nih.gov/pubmed/
- World Bank Library Network: http://jolis.worldbankimflib.org/e-nljolis.htm
- Central Intelligence Agency, United States, Official website: https://www.cia.gov

- FIOCRUZ: http://www.ensp.fiocruz.br/portal-ensp/informe/site/materia/detalhe/24720
- Access to Pharmaceuticals: http://www.accesstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/
- New England Journal of Medicine: http://www.nejm.org/

XII. Endnotes

[1] Aquisição de Medicamentos para Assistência Farmacêutica no SUS, Orientações Básicas, Ministério da Saúde, Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Brasília – DF, 2006, p.11, http://portal.saude.gov.br/portal/arquivos/pdf/aquisicao_medicamentosfinal.pdf, accessed March 12, 2012

[2] Iunes, Roberto, Sarti, Flavia M., Coelho Campino, Antonio Carlos, Diaz, Maria Dolores M., Sierra, Ricardo: Assessing financial protection and equity under the Brazilian national health care system, Economic Research Foundation (FIPE)/ Inter-American Development Bank, 2011 (not officially published)

[3] Article 196 of the Federal Constitution of 1988

[4] Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.

[5] Pepe, Vera Lúcia Edais *et al.* Caracterização de demandas judiciais de fornecimento de medicamentos „essenciais no Estado do Rio de Janeiro, Brasil. Cad. Saúde Pública. Rio de Janeiro, v. 26, n. 3, mar. 2010.

[6] Vieira, F. and Zucchi, P., "Distorções causadas pelas ações judiciais à política de medicamentos no Brasil" ("Distortions to national drug policy caused by lawsuits in Brazil"), Revista de Saúde Pública 41/2 (2007), pp. 214–222

[7] http://www.who.int/topics/essential_medicines/en/

[8] Ventura, Miriam; Simas, Luciana, Pepe, Vera Lúcia Edais, Schramm, Fermin Rolan, Judicialização da saúde, acesso à justiça e a efetividade do direito à saúde, Physis Revista de Saúde Coletiva, Rio de Janeiro, 20 [1]: 77-100, 2010

[9] Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.

[10] Idem

[11] Bassette, Fernanda, RS reúne metade das ações judiciais de saúde - O Estado de S.Paulo, April 29th 2011, http://www.estadao.com.br/noticias/impresso,rs-reune-metade-das-acoes-judiciais-de-saude,712418,0.htm, accessed April 2, 2012

[12] Biehl, João, Petryna, Adriana, Gertner, Alex, Amon, Joseph J., Picon, Paulo D., Judicialização do direito à saúde no Brasil, in: Tânia Margarete Mezzomo Keinert, Silvia Helena Bastos de Paula, José Ruben de Alcântara Bonfim, As ações judiciais no SUS e a promoção do direito à saúde, Instituto de Saúde, São Paulo, 2009, p.147f., Accessible: http://www.isaude.sp.gov.br/smartsitephp/media/isaude/file/acoesjudiciais.pdf

[13] Bassette, Fernanda, RS reúne metade das ações judiciais de saúde - O Estado de S.Paulo, April 29th 2011, http://www.estadao.com.br/noticias/impresso,rs-reune-metade-das-acoes-judiciais-de-saude,712418,0.htm, accessed April 2, 2012

[14] Idem
[15] Iunes, Roberto, Sarti, Flavia M., Coelho Campino, Antonio Carlos, Diaz, Maria Dolores M., Sierra, Ricardo: Assessing financial protection and equity under the Brazilian national health care system, Economic Research Foundation (FIPE)/ Inter-American Development Bank, 2011 (not published)
[16]Alves, Alessandra Vanessa, Atuação da consultoria jurídica do ministerio da saúde nas demandas judiciais da saúde, Coordenadora Geral de Assuntos Jurídicos, AGU: From CDJU – Coordenação de Demanda Judicial: http://www.cnj.jus.br/images/programas/forumdasaude/papeldaconjurnasacoesdesaude.pdf, accessed March 27, 2012
[17] idem
[18] Collucci, C., Triplicam as ações judiciais para obter medicamentos. Folha de São Paulo, São Paulo, 01 de janeiro de 2009**:** http://www.sindifarmajp.com.br/noticias.php?not_id=765 , accessed February 2, 2012
[19] For a discussion of decentralization and its difficulties, see Spedo, Sandra Maria et al., O desafio da descentralização do Sistema Único de Saúde em município de grande porte: o caso de São Paulo, Brasil, Cad. Saúde Pública vol.25 no.8 Rio de Janeiro Aug. 2009, Access: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102
[20] All currency exchanges taken for the year for which data was obtained, using www.imf.org
[21] Alves, Alessandra Vanessa, Atuação da consultoria jurídica do ministerio da saúde nas demandas judiciais da saúde, Coordenadora Geral de Assuntos Jurídicos, AGU: From CDJU – Coordenação de Demanda Judicial: http://www.cnj.jus.br/images/programas/forumdasaude/papeldaconjurnasacoesdesaude.pdfx
[22] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011.
[23] Figueiredo TA**.** Análise dos medicamentos fornecidos por mandado judicial na Comarca do Rio de Janeiro: A aplicação de evidências científicas no processo de tomada de decisão [dissertação]. Rio de Janeiro (RJ): Escola Nacional de Saúde Pública Sérgio Arouca. Fundação Oswaldo Cruz; 2010.
[24] This literature review has been conducted with the input of judicialization researcher Vera Pepe (FIOCRUZ) through e-mail correspondence, Fernanda Terrazas (see interviews) and right to health professor at University of Sao Paulo, Sueli Dallari (see interviews)
[25] Lopes, L. C., Barberato Filho, S, Polimeno, N.C., Costa, A.C., Naffah Filho, M., Correa, M.C., Osorio-de-Castro, C.G.S. Medicamentos antineoplásicos e ações judiciais: contribuição para o modelo de assistência farmacêutica no SUS. In: Seminário: Programa de Pesquisa para o Sistema Único de Saúde (PPSUS-SP) 2004-2007, 2008, São Paulo. Relatório de resultados dos projetos de pesquisa/Seminário PPSUS-SP, 2008
[26] Vieira, F. and Zucchi, P., "Distorções causadas pelas ações judiciais à política de medicamentos no Brasil" ("Distortions to national drug policy caused by lawsuits in Brazil"), *Revista de Saúde Pública* 41/2 (2007), pp. 214–222
[27] Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.
[28] Correspondence with Vera Lúcia Edais Pepe, see publications
[29] Sacco, Renata Dos Anjos, judicialização e equidade no tratamento da hepatite C: estudo do caso sobre o tratamento com interferona alfa em um serviço de referencia do SUS em Porto Alegre, RS, UFRGS, Faculdade de medicina, Porto Alegre, 2009

[30] Loyola, Maria Andréa. Medicamentos e saúde pública em tempos de AIDS: metamorfoses de uma política dependente. Ciênc. saúde coletiva, Rio de Janeiro, 2011. Link: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1413-81232008000700027&lng=en&nrm=iso. accessed March 1, 2012

[31] Messeder, Ana Marcia, Osorio-de-Castro, Claudia G.S., Luiza, Vera Lucia, Mandados judiciais como ferramenta para garantia do acesso a medicamentos no setor público: a experiência do Estado do Rio de Janeiro, Brasil. Cad Saude Publica 2005; 21(2):525-534.

[32] Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.

[33] idem

[34] idem

[35] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011.

[36] Statement by Prof. Sueli Dallari, Information obtained in personal interview in March 2012.

[37] http://www.scielosp.org/

[38] http://regional.bvsalud.org/php/index.php?lang=en

[39] http://www.scielosp.org/

[40] http://regional.bvsalud.org/php/index.php?lang=en

[41] http://www.jstor.org/

[42] http://www.sciencedirect.com/

[43] http://www.ncbi.nlm.nih.gov/pubmed/

[44] http://jolis.worldbankimflib.org/e-nljolis.htm

[45] http://www.ibge.gov.br/cidadesat/topwindow.htm?1

[46] All information on medicines dispensed via the Courts was obtained from the Department of Health of Rio de Janeiro.

[47] Figueiredo TA**.** Análise dos medicamentos fornecidos por mandado judicial na Comarca do Rio de Janeiro: A aplicação de evidências científicas no processo de tomada de decisão [dissertação]. Rio de Janeiro (RJ): Escola Nacional de Saúde Pública Sérgio Arouca. Fundação Oswaldo Cruz; 2010.

[48] Tribunal of Justice/ Rio de Janeiro and “Central de Mandados” of the State Secretary of Health of the State of Rio de Janeiro (SESDEC/RJ) in: see Figueiredo in endnote 46

[49] Pereira, Januária Ramos; Santos, Rosana Isabel dos; Nascimento Junior, José Miguel do and Schenkel, Eloir Paulo. Análise das demandas judiciais para o fornecimento de medicamentos pela Secretaria de Estado da Saúde de Santa Catarina nos anos de 2003 e 2004. *Ciênc. saúde coletiva* [online]. 2010, vol.15, suppl.3, pp. 3551-3560. ISSN 1413-8123

[50] Vieira, Fabiola Sulpino and Zucchi, Paula, “Distorções causadas pelas ações judiciais à política de medicamentos no Brasil” (“Distortions to national drug policy caused by lawsuits in Brazil”), Revista de Saúde Pública 41/2 (2007), pp. 214–222

[51] Messeder, Ana Marcia, Osorio-de-Castro, Claudia G.S., Luiza, Vera Lucia, Mandados judiciais como ferramenta para garantia do acesso a medicamentos no setor público: a experiência do Estado do Rio de Janeiro, Brasil. Cad Saude Publica 2005; 21(2):525-534

[52] Romero, Luiz Carlos, Judicialização das políticas de assistência farmacêutica: o caso do distrito federal. Brasília: Consultoria Legislativa do Senado Federal; 2008.

[53] Pepe, Vera Lúcia Edais et al., A judicialização no acesso a medicamentos no estado do Rio de Janeiro: um olhar sobre o essencial. Relatório final de pesquisa (projeto de pesquisa financiada pela Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de

Janeiro – FA-PERJ). Rio de Janeiro, Escola Nacional de Saúde Pública Sérgio Arouca/Fiocruz, 2008.

[54] Pepe, Vera Lúcia Edais et al., Characterization of lawsuits for the supply of essential medicines in the State of Rio de Janeiro, Brazil, National School of Public Health, Oswaldo Cruz Foundation, presented at HTAi 2011: http://www.htai2011.org/documentos/911%20VP.pdf

[55] Pepe, Vera Lúcia Edais et al., A judicialização da saúde e os novos desafios da gestão da assistência farmacêutica, Ciência & Saúde Coletiva, 15(5):2405-2414, 2010, p.2409f.

[56] Figueiredo, Tatiana de Aragão et al.; Análise dos medicamentos fornecidos por mandado judicial na Comarca do Rio de Janeiro: A aplicação de evidências científicas no processo de tomada de decisão. Dissertação apresentada à Escola Nacional de Saúde Pública Sergio Arouca como requisito parcial para obtenção de título de Mestre em Saúde Pública. Rio de Janeiro, 2010.

[57] Amaral de Ávila Machado, Marina; Acúrcio, Francisco de Assis; Brandão, Cristina Mariano Ruas; Faleiros, Daniel Resende; Guerra Júnior, Augusto Afonso; Cherchiglia, Mariangela Leal; Andrade, Eli Iola Gurge, Judicialização do acceso de medicamentos no Estado de Minas Gerais, Brasil, Rev Saúde Pública 2011;45(3):590-8

[58] Vieira, Fabiola Sulpino and Zucchi, Paula, "Distorções causadas pelas ações judiciais à política de medicamentos no Brasil" ("Distortions to national drug policy caused by lawsuits in Brazil"), Revista de Saúde Pública 41/2 (2007), pp. 214–222

[59] Chieffi, Ana Luiza, Barata, Rita Barradas, Judicialização da política pública de assistência farmacêutica e eqüidade. Cad. Saúde Pública 2009 Ago; 25(8):1839-1849. Santos L. SUS: contornos jurídicos da integralidade da atenção à saúde. Radis Comunicação em Saúde 2006; (49). Access: http://www.ensp.fiocruz.br/radis/49/web-02.html (acessado em 25/Jul/2008).

[60] Andrade, Eli Iola Gurge; Machado, Carlos Dalton; Faleiros, Daniel Resende; Szuster, Daniele Araújo Campos, Guerra Júnior, Augusto Afonso; Dias da Silva, Grazielle; Cherchiglia, Mariangela Leal; Acúrcio, Francisco de Assis, A judicialização da saúde e a politica nacional de assisência farmacêutica no Brasil: gestão da clinica e medicalização da justiça, Rev Med Minas Gerais 2008; 18(46 4 Supl 4): 46-50

[61] Pepe, Vera Lúcia Edais et al., A judicialização da saúde e os novos desafios da gestão da assistência farmacêutica, Ciência & Saúde Coletiva, 15(5):2405-2414, 2010

[62] Ministério da Saúde, Política Nacional de medicamentos, Ministério da Saúde, Secretaria de Políticas de Saúde, Departamento de Formulação de Políticas de Saúde, Brasília, maio de 2001

[63] http://portal.saude.gov.br/portal/arquivos/pdf/Diretrizes_Nacionais_Rename_Forum_AF.pdf

[64] Sant'Ana, Joao Mauricio Brambati, Pepe, Vera Lúcia Edais, Osorio-de-Castro, Claudia Garcia Serpa, Ventura, Miriam, Essencialidade e assistência farmacêutica: considerações sobre o acesso a medicamentos mediante ações judiciais no Brasil, Revista Panamericana de Salúd Publica, 29 (2), 2011.

[65] Barroso, Luís Roberto, Da falta de efetividade à judicialização excessiva: Direito à saúde, fornecimento gratuito de medicamentos e Parâmetros para a atuação judicial

[66] http://www.ensp.fiocruz.br/portal-ensp/judicializacao/pdfs/288.pdf

[67] Pepe, Vera Lúcia Edais *et al.* Caracterização de demandas judiciais de fornecimento de medicamentos „essenciais no Estado do Rio de Janeiro, Brasil. Cad. Saúde Pública. Rio de Janeiro, v. 26, n. 3, mar. 2010.

[68] Series of interviews with UERJ professors and Municipal Health Secretariat of Rio de Janeiro in April 2012 (see annex for interview schedule)

[69] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.53

[70] Previously named medicines of exceptional character, amended by Ministerial Directive MS / GM No. 2981 of November 26, 2009

[71] http://portal.saude.gov.br/portal/saude/profissional/area.cfm?id_area=1349 and http://bvsms.saude.gov.br/bvs/publicacoes/documenta3.pdf, accessed May 1, 2012
[72] Information obtained from Rondineli Mendes, Secretariat of Health of the municipality of Rio de Janeiro
[73] Idem
[74] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.54
[75] http://portalsaude.saude.gov.br/portalsaude/noticia/4603/162/relacao-nacional-de-medicamentos-quase-dobra.html, accessed May 1, 2012
[76] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.54
[77] Ombaka, Eva, Current status of medicines procurement, *American Journal of Health-System Pharmacy* March 1, 2009 vol. 66 no. 5 Supplement 3 p. 20-28, http://www.ajhp.org/content/66/5_Supplement_3/s20.full, accessed March 2, 2012
[78] See interview schedule in annex
[79] Pepe, Vera Lúcia Edais et al., A judicialização da saúde e os novos desafios da gestão da assistência farmacêutica, Ciência & Saúde Coletiva, 15(5):2405-2414, 2010, p.2408f.
[80] Terrazas, Fernanda Vargas, Os Impactos Da Judicialização Da Saúde No Orçamento Público Da Saúde: O Caso Do Município De São Paulo / The Impact Of Health Litigation On The Public Health Budget: The Case Of The City Of São Paulo, unpublished paper
[81] Data sheet obtained from the Municipal Health Secretariat of Rio de Janeiro in April 2012
[82] Pepe, Vera Lúcia Edais et al., Characterization of lawsuits for the supply of essential medicines in the State of Rio de Janeiro, Brazil, National School of Public Health, Oswaldo Cruz Foundation, presented at HTAi 2011: http://www.htai2011.org/documentos/911%20VP.pdf
[83] Terrazas, Fernanda Vargas, Os Impactos Da Judicialização Da Saúde No Orçamento Público Da Saúde: O Caso Do Município De São Paulo / The Impact Of Health Litigation On The Public Health Budget: The Case Of The City Of São Paulo, unpublished paper
[84] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.51
[85] Vianna, Luiz Werneck, Burgo, Baumann Burgos. Entre princípios e regras: cinco estudos de caso de ações civis públicas. / Principles and rules: five case studies of class action suits in Brazil, Dados – Revista de Ciências Sociais 2005; 48(4): 777-843, available at: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0011-52582005000400003
[86] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.51
[87] Romero, Luiz Carlos, Judicialização das políticas de assistência farmacêutica: o caso do distrito federal. Brasília: Consultoria Legislativa do Senado Federal; 2008.
[88] Messeder, Ana Marcia, Osorio-de-Castro, Claudia G.S., Luiza, Vera Lucia, Mandados judiciais como ferramenta para garantia do acesso a medicamentos no setor público: a experiência do Estado do Rio de Janeiro, Brasil. Cad Saude Publica 2005; 21(2):525-534.
[89] Geocze, Luciana et al. Qualidade de vida e adesão ao tratamento anti-retroviral de pacientes portadores de HIV. Rev. Saúde Pública [online]. 2010, vol.44, n.4 [cited 2012-06-02], pp. 743-749 .
[90] Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.

[91] TJRJ, j. 20 set. 1994, Apelação Cível 1994.001.01749, Rel Des. Carpena Amo
[92] Ferraz, Octavio Luiz Motta, The right to health in the courts of Brazil: worsening health inequities?, Health and Human Rights: An International Journal 11/2 (2009), pp. 33–45. Available at http://www.hhrjournal.org/index.php/hhr/article/viewArticle/172, accessed May 1, 2012
[93] Gloppen, Siri, Litigation as a strategy to hold governments accountable for implementing the right to health, Health and Human Rights: An International Journal 10/2 (2009), pp. 21–36. Available at http://hhrjournal.org/index.php/hhr/article/view/79/164, accessed May 1, 2012
[94] Afonso da Silva, Virgílio, Vargas Terrazas, Fernanda, Claiming the Right to Health in Brazilian Courts: The Exclusion of the Already Excluded?, Law & Social Inquiry Law & Social Inquiry, Volume 36, Issue 4, pages 825–853, Fall 2011, http://onlinelibrary.wiley.com/doi/10.1111/j.1747-4469.2011.01252.x/references, accessed May 18, 2012
[95] Figueiredo TA**.** Análise dos medicamentos fornecidos por mandado judicial na Comarca do Rio de Janeiro: A aplicação de evidências científicas no processo de tomada de decisão [dissertação]. Rio de Janeiro (RJ): Escola Nacional de Saúde Pública Sérgio Arouca. Fundação Oswaldo Cruz; 2010.
[96] Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.
[97] Idem
[98] Idem
[99] Idem
[100] Fleury, Sonia. "A questão democrática na Saúde". In: Fleury, Sonia (Org.) Saúde e Democracia: a luta do Cebes. São Paulo: Lemos Editorial, 1997. In: Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.24
[101] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.26
[102] Santos CC, Guimarães LG, Gonçalves SA. Estratégias para reorganização e otimização das atividades destinadas ao fornecimento de medicamentos demandados judicialmente contra a Secretaria de Estado de Saúde do Distrito Federal [monografia de especialização]. Brasília (DF): Faculdade de Ciências da Saúde, Universidade de Brasília; 2006.
[103] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011.
[104] Idem
[105] Idem
[106] Idem
[107] 2012 Portal da Saude do RJ - SES - Secretaria de Estado de Saúde http://www.saude.rj.gov.br/i, accessed June 2, 2012
[108] Teixeira, Mariana Faria, Criando alternativas ao processo de judicialização da saúde: o sistema de pedido administrativo, uma iniciativa pioneira do estado e município do Rio de Janeiro, Ministerio da Saude, FIOCRUZ, Rio de Janeiro, março de 2011, p.48
[109] idem
[110] interviews

[111] Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.
[112] A website by the World Bank Institute has been conceived in September 2011 to report on judicializatio of the right to health in seven Latin American countries and beyond, and to engage stakeholders into the debate. It is part of the Regional Initiative on Priority-Setting, Equity and Constitutional Mandates, which has been bringing together actors of all seven countries in region-wide knowledge exchange meetings. www.saluderecho.net
[113] Hoffman, F and Bentes, F., Accountability for social and economic rights in Brazil, in: V. Gauri and D. Brinks (eds), *Courting social justice: Judicial enforcement of social and economic rights in the developing world* (Cambridge, UK: Cambridge University Press, 2008), pp. 100–145.
[114] Classification to emerging country list according to World Bank: http://data.worldbank.org/about/country-classifications, accessed June 6, 2012
[115] Central Intelligence Agency, United States, Official website: https://www.cia.gov/library/publications/the-world-factbook/fields/2010.html, accessed June 4, 2012, accessed May 1, 2012
[116] idem
[117] Araújo LU, Albuquerque KT, Kato KC, Silveira GS, Maciel NR, Spósito PÁ, Barcellos NM, Souza J, Bueno M, Storpirtis S., Generic drugs in Brazil: historical overview and legislation, Rev Panam Salud Publica. 2010 Dec;28(6):480-92. Link: http://www.ncbi.nlm.nih.gov/pubmed/21308175, accessed June 5, 2012
[118] http://www.accesstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/, accessed June 5, 2012
[119] New England Journal of Medicine: http://www.nejm.org/doi/full/10.1056/NEJMp068069, accessed June 5, 2012
[120] Information obtained in interview with Sueli Dallari in March in Paris (see interview schedule)
[121] Barroso, Luís Roberto, Da falta de efetividade à judicialização excessiva: Direito à saúde, fornecimento gratuito de medicamentos e Parâmetros para a atuação judicial
[122] Pepe, Vera Lucia Edais e Ventura, Miriam (org.); com a colaboração de Claudia Garcia Serpa Osorio-de-Castro. Instituto de Comunicação e Informação Científica e Tecnológica Biblioteca de Saúde Pública, Indicadores de avaliação e monitoramento das demandas judiciais de medicamentos, Manual 2011. Rio de Janeiro: Fundação Oswaldo Cruz, Escola Nacional de Saúde Pública Sergio Arouca, 2011
[123] http://www.ensp.fiocruz.br/portal-ensp/informe/site/materia/detalhe/24720, accessed May 17, 2012
[124] Ministério da Saúde, Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Departamento de Assistência Farmacêutica e Insumos Estratégicos, Assistência farmacêutica na atenção básica: instruções técnicas para sua organização – 2. ed. – Brasília : Ministério da Saúde, 2006. 100 p.: il. – (Série A. Normas e Manuais Técnicos)